

NORTH CAROLINA DEPARTMENT OF HEALTH  
AND HUMAN SERVICES

COMMUNICABLE DISEASE BRANCH

PREVENTION PROGRAM



**RAPID TESTING  
PROGRAM MANUAL  
AND QUALITY  
ASSURANCE  
PROTOCOL FOR STATE  
PURCHASED RAPID  
HIV/HCV/STD TEST  
KITS AND CONTROLS**

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## THE NC DHHS RAPID TESTING PROGRAM

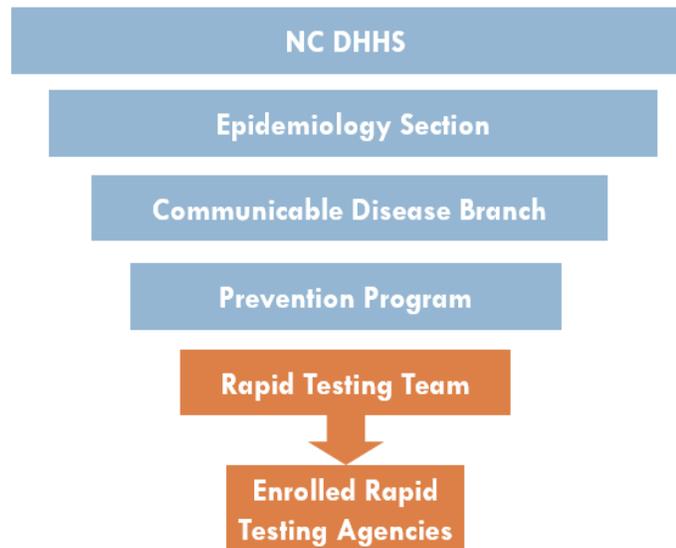
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As this guide is meant to be comprehensive, it is still understood that a testing agency might have more questions associated with the program and its requirements. This manual is meant to serve as a guide in which each agency can use to create an adapted program that both fulfills the protocols of the NC DHHS and fits the needs of the communities served. For more valuable insight into the program and viable contact information, please visit the [NC DHHS Communicable Disease website](#).

To prevent and control HIV and other sexually transmitted diseases, the North Carolina Department of Health and Human Services (NC DHHS) supports confidential free testing and treatment in many diverse settings around the state. These include NC federally qualified health centers (FQHC), community-based organizations (CBOs), 340B eligible agencies (agencies do not have to receive direct funding to be a part of the NC DHHS Rapid Testing Program), nonprofits, local health departments, Syringe Exchange Sites, Disease Intervention Specialists (DIS), colleagues, and correctional facilities.

As a part of the Communicable Disease Branch, the HIV Prevention Program assists these agencies by providing free rapid testing technologies and other prevention materials for use in both their clinical and outreach environments.

The Rapid Testing Program began in 2004 with 10 enrolled agencies and steadily grew over the years to accommodate 65, reaching almost every area of the state. At the start, the Rapid Testing Program offered one brand of HIV rapid test. Today, the program has grown to accommodate funded and non-funded agencies and provides HIV, hepatitis C, and syphilis rapid testing technologies. This document is meant to act as a “one-stop-shop” program manual for all aspects involved with the NC DHHS Communicable Disease Prevention Rapid Testing Program. You will find instructions for applying to the program and requesting testing items, quality assurance requirements, reporting instructions, and information on annual trainings.



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## 340B PRICING ELIGIBILITY INFORMATION

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The 340B Drug Pricing Program enables covered entities to stretch scarce federal resources as far as a possible, reaching more eligible patients and providing more comprehensive services.\*

In order to access 340B pricing, the Communicable Disease can confer 340B eligibility by giving an entity funds or in-kind support from one of the Section 318 eligible grants. One mechanism to provide in kind services is sending an agency supplies such as syphilis rapid test kits and confirming with HRSA that your agency receives the necessary in-kind support for eligibility. This provision of supplies or funds only confers eligibility. It is then up to the agency to apply through HRSA and meet the requirements of becoming a 340B covered entity and also to comply with all HRSA post approval requirements. The Communicable Disease Branch cannot assist with the application or meeting of requirements.

Being a 340B covered entity requires detailed inventory tracking to ensure appropriate use. 340B programs can be audited at any time. The CD Branch would like to take this opportunity to highlight just a few 340B requirements for covered entities. The full scope of requirements is available from HRSA throughout the 340B program website at <https://www.hrsa.gov/opa/index.html>. A covered entity must, among other requirements:

- **Keep 340B OPAIS information accurate and up to date.** Register new outpatient facilities and contract pharmacies as they are added.
- **Recertify eligibility every year.** If there is a change in a covered entity's eligibility status, the covered entity has a responsibility to immediately notify OPA and should stop purchasing drugs through the 340B Program.
- **Prevent diversion to ineligible patients.** Covered entities must not use, resell or otherwise transfer 340B drugs to ineligible patients.
- **Duplicate Discount Prohibition.** Manufacturers are prohibited from providing a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities must accurately report how they bill Medicaid fee-for-service drugs on the Medicaid Exclusion File, as mandated by 42 USC 256b(a)(5)(A)(i).
- **Prepare for program audits.** Maintain auditable records documenting compliance with 340B Program requirements. Covered entities are subject to audit by manufacturers or the federal government. Any covered entity that fails to comply with 340B Program requirements may be liable to manufacturers for refunds of the discounts obtained.

See the FAQ and Prevention of Diversion Self Audit Tool from Apexus to aid you in assessing your entity's ability to maintain a 340B compliant program [on pages 26-34](#). Also included is a sample letter of agreement from the CD Branch that you will be asked to sign before being authorized by the CD Branch for 340B eligibility [on page 35](#). The HRSA training linked here: <https://www.brainshark.com/apexus/340BTheBasics?&pause=1&nrs=1> may also be of use to those interested in 340B eligibility.

\*Taken from the Health Resources & Services Administration [website](#)

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## APPLYING TO THE PROGRAM

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The North Carolina Department of Health and Human Services (NC DHHS) supports many different types of HIV and STD rapid testing agencies with rapid testing supplies, prevention supplies, and programmatic assistance. These agencies include, but are not limited to local health departments, community-based organizations (CBOs), Federally Qualified Health Centers (FQHCs), syringe exchange programs, and university-based testing centers.

To apply for the program, an agency (big or small) should complete an application (copy on [pages 43-45](#)) and send the completed form via email to a Rapid Testing Team member: Marti Eisenberg ([marti.eisenberg@dhhs.nc.gov](mailto:marti.eisenberg@dhhs.nc.gov)/919-755-3145) or Carlotta McNeill ([carlotta.mcneill@dhhs.nc.gov](mailto:carlotta.mcneill@dhhs.nc.gov)/919-755-3144). If you have any questions on the application or any area of the program, reach out to a Rapid Testing Team member and they will assist you.

### The Application

A testing program must complete an application in order to receive free rapid test items and other prevention supplies. Below is a list of requirements that must be fulfilled in order to be accepted into the NC DHHS Rapid Testing Program.

#### NC DHHS Rapid Testing Requirements

##### 1. CLIA (Clinical Laboratory Improvement Amendments) Certificate of Waiver

The purpose of a CLIA is to set minimum standards for laboratories and testing sites to follow and to ensure that these laboratories are achieving these standards. CLIA provides a “limited public health use” exception, under which a licensed laboratory can operate multiple satellite sites under the umbrella of a single CLIA certificate. Applications for this certificate and license can be found through the Division of Health Service Regulation. Information can be found online at: <http://www.ncdhhs.gov/dhsr/ahc/cli/index.html> or via phone at 919-855-4620.

##### 2. HIV Testing License

Applications for this certificate and license can be found through the Division of Health Service Regulation. Information can be found online at <https://info.ncdhhs.gov/dhsr/ahc/cli/pdf/hivapp.pdf> or via phone at 919-855-4620. A copy of the most recent HIV Testing License application is also found on [pages 46-47](#).

##### 3. Medical Provider and Standing Order

Each testing agency must work under a medical provider’s standing orders or policies and procedures which ensure that the testing site is providing appropriate testing services to their client population. An example of a standing order is on [page 65](#).

##### 4. Confirmation of Positive Test Results

Each testing agency must have a process in place to confirm preliminary HIV positive rapid test results (first rapid test taken for an individual revealing an initial positive result). Confirmation can be done by either exercising “Dual Protocol” (utilizing a different HIV rapid test brand directly after the initial rapid test is administered) or by taking a whole blood sample through means of phlebotomy (and sending it to the confirmed laboratory of choice).

You can choose either the Dual Protocol method or whole blood method. If the agency does not have any staff that are trained in phlebotomy, then the agency can opt to house at least two different brands of HIV rapid test and train their testing staff on each brand. This will enable the agency to properly perform dual protocol. More information on Dual Protocol can be found on [page 18](#).

The whole blood confirmation method involves providing phlebotomy services. The State offers free phlebotomy courses to individuals working for funded and supported testing agencies. These courses take place throughout the year with limited slots available. If interested in enrolling a staff member in a phlebotomy class, contact Marti Eisenberg at [marti.eisenberg@dhhs.nc.gov](mailto:marti.eisenberg@dhhs.nc.gov).

#### 5. Referral Network

Each testing agency must describe their process for linking preliminary positive clients to care, treatment and support services, and include a list of referral networks. Linkage to care should consist of the following:

- Partnerships with local health departments and regional Network of Care Providers to secure appropriate HIV/AIDS support resources including laboratory services;
- HIV/AIDS primary and behavioral health care services;
- Other necessary support services (insurance, housing, food, transportation).

#### 6. Training

Each testing agency must list staff members who have been trained in Rapid Testing and/or Counseling, Testing and Referral. If staff have not been trained, agencies must submit their training needs as indicated on [pages 22-23](#).

Note: Once enrolled, agencies must enroll in a proficiency testing program or create their own agency specific proficiency and quality assurance plan as noted on [pages 14-16](#). All rapid testing plans will be reviewed by the Rapid Testing Team at the specified site visit. Specific information regarding these plans are detailed throughout this manual.

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## RAPID TESTING AND PREVENTION SUPPLIES OFFERED

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The NC DHHS HIV Prevention Program currently offers three different brands of HIV rapid tests, one brand of hepatitis C rapid tests, and one brand of syphilis rapid tests. Each company and type of test is listed below. The Prevention Program also routinely carries prevention items such as condoms, lubricant, and dental dams.

### Rapid Tests

#### OraSure Technologies OraQuick Advance Rapid HIV-1/2 Antibody Test (OraQuick HIV)



- OraQuick test specimens can be oral fluid, finger-stick whole blood, venipuncture whole blood, or plasma with results interpreted between 20-40 minutes.
- Kit consists of a single-use test device and developer solution, a reusable test stand, and a disposable single-use specimen collection loop
- A control will also be supplied (refrigeration upon arrival)

#### Alere Determine HIV 1/2 Ag/Ab Combo (“Determine”)

- Determine test specimens can be finger-stick whole blood, venipuncture whole blood, serum, or plasma with results interpreted between 20-30 minutes
- Kit consists of a single-use testing device and chase buffer, a disposable single-use capillary tubes for finger-stick specimen collection, and a disposable workstation
- A control will also be supplied (refrigeration upon arrival)



#### bioLytical INSTI HIV-1/ HIV-2 Rapid Antibody Test (“INSTI”)



- INSTI tests specimens can be finger-stick whole blood, venipuncture whole blood, or plasma with results being interpreted in 60 seconds
- Kit consists of a membrane unit, a sample diluent, a color developer, a clarifying solution, a single use pipette, a lancet, and a package insert
- A control will also be supplied (refrigeration upon arrival)

### Diagnostic Direct Syphilis Health Check (“Syphilis Health Check”)



- Syphilis Health Check test specimens can be finger-stick whole blood, serum, or plasma with results interpreted between 10-15 minutes.
- Kit consists of 20 test devices, 20 plastic pipettes, diluent dropper bottle, and quick reference instructions
- A control will also be supplied (refrigeration upon arrival)

### OraQuick HCV Rapid Antibody Test (“OraQuick HCV”)

- OraQuick test specimens can be oral, finger-stick whole blood, serum, or plasma with results interpreted between 20-40 minutes.
- Kit consists of a single-use test device and developer solution, a reusable test stand, and a disposable single-use specimen collection loop



### Prevention Supplies

- Latex Condoms
- Unflavored Lubricant
- Flavored Dental Dams

\*The NC DHHS offers prevention supplies throughout the year. Contact the Rapid Testing Monitor to find out what is currently in stock. Contact information is listed on the last page of this manual.

### Additional Rapid Testing Items

Agencies must purchase the following items to properly conduct HIV/STD rapid testing:

- Disposable absorbent workspace covers
- Biohazard waste disposal bags
- Latex/polyurethane/nitrile gloves
- Sharps container (for blood specimen testing only)
- Disposable lancets (for blood specimen testing only)
- Thermometers (one for the storage area, one for the refrigerator, one for mobile sites)
- Timers
- 10% bleach solution or FDA approved disinfectant
- Other materials deemed necessary

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## INSTRUCTIONS FOR ORDERING

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Once an agency has been accepted into the program, rapid test kits, controls for the rapid tests, and prevention supplies can be requested. All requests should be made through the HIV Prevention Program. Rapid tests and prevention supplies are housed at the Raleigh, NC based NC DHHS Communicable Disease office building and are distributed by the Rapid Testing Team. Controls are distributed by the State Lab of Public Health also located in Raleigh, NC. Below you will find specific instructions and detailed information for ordering.

### Ordering Process

1. An agency must contact a member of the Rapid Testing Team (Rapid Testing Coordinator) by phone or by email (information below).
  - Carlotta McNeill ([carlotta.mcneill@dhhs.nc.gov](mailto:carlotta.mcneill@dhhs.nc.gov) / 919-755-3144)
  - Marti Eisenberg ([marti.eisenberg@dhhs.nc.gov](mailto:marti.eisenberg@dhhs.nc.gov) / 919-755-3145)
  - Rapid Testing Monitor (919-755-3153)
  
2. Message Contents
  - Rapid Tests/Controls
    - Within the request, the agency representative must specify how many boxes of which brand and how many controls are needed. It is not guaranteed that an agency will receive the full request amount, but the team will do the best they can to send the full request.
  - Prevention Items
    - Within the request, the agency representative must specify if they would like prevention supplies, and which type, condoms, lubricant, or dental dams. At times, the supply varies depending on State supported contracts. Check with the Rapid Testing Team about what items are in stock.
  
3. Confirmation
  - A Rapid Testing Coordinator will respond and confirm your request. They will reply with how many items will be sent and the expected date of delivery.
  
4. Shipment Dates
  - Rapid Tests/Prevention Supplies
    - All test kits and prevention supplies are housed at the NC DHHS Communicable Disease Front Street office (1200 Front Street) and distributed, depending on supply, by the Rapid Testing Team on either Tuesday or Wednesday of each week.
  - Controls
    - Brand specific controls that match the test kits are sent along with every test kit order unless the agency already has enough controls.
    - Controls are shipped by the State Lab of Public Health (SLPH) in Raleigh, NC. An agency does NOT need to contact the SLPH to receive controls; the Rapid Testing Team is the only agency that contacts the SLPH to request controls.
    - Controls will be shipped within the week, usually on Wednesdays or Thursdays in insulated packaging.

## 5. Upon Receiving

- Rapid Test/Prevention Supplies
  - Rapid tests and prevention supplies must be stored at room temperature (specific temperatures for each brand of test kit are specified in the Rapid HIV HCV Syphilis Testing Comparison Chart on [page 56](#)).
- Controls
  - Once received, the shipment of controls must be **refrigerated immediately**. If a control arrives room temperature or is damaged, contact a Rapid Testing Coordinator and a new control will be sent.
  - Email a confirmation of receipt to the Rapid Testing Program Monitor (contact information on [page 66](#)) once the controls arrive.
- Vendor Direct Shipments
  - Once a vendor direct shipment is received, the packing slip/invoice must be immediately scanned and then sent to a Rapid Testing Program Monitor.

## QUALITY ASSURANCE REQUIREMENTS

Once an agency has begun testing, it is required that essential quality assurance measures are carried out and recorded. Each required process is detailed below. If any questions arise, it is the agency's responsibility to contact a Rapid Testing Coordinator.

### Test Kits and Controls:

#### 1. Temperature Monitoring

Test kits and controls must be monitored at least once a week to ensure testing supplies are maintained at an adequate temperature. Temperatures are to be documented in their respective temperature logs (examples included in the reference section in the back of the packet on [pages 58 and 59](#)). The specific temperatures that each brand of test kit and control are specified below.

The room temperature must also be recorded at the testing location on the day of testing. If testing is performed in a temperature-controlled environment, the temperature may be recorded once at the beginning of testing. If testing is performed outdoors or in a noncontrolled environment, the temperature should be recorded at frequent intervals to ensure the testing environment does not exceed the specific kit temperature requirements.

		<b>OraSure Technologies OraQuick <i>ADVANCE</i>® Rapid HIV-1/2 Antibody Test</b>	<b>Alere Determine™ HIV- 1/2 Ag/Ab Combo</b>	<b>Diagnostics Direct Syphilis Health Check™</b>	<b>OraSure Technologies OraQuick® HCV Rapid Antibody Test</b>	<b>INSTI HIV-1/HIV-2 Antibody Test</b>
Requirements		(35° to 46°F)	(35° to 46°F)	(35° to 46°F)	(35° to 46°F)	(35.6°-86°F)
	Test Kit Storage	2 to 27°C (35° to 80°F)	2 to 30°C (35° to 86°F)	4° to 30°C (39.2°-86°F)	2° to 30°C (35.6°-86°F)	2 to 30°C (35° to 86°F)
	Testing Environment	15° to 37°C (59° to 99°F)	15° to 30°C (59° to 86°F)	20° to 26°C (68° to 78.8°F)	15° to 37°C (59° to 99°F)	15° to 30°C (59°-86°F)

#### 2. Running Controls

A control must be run under each of the following circumstances:

- Each newly trained counselor prior to performing rapid testing on client specimens
- When opening a new test kit lot (lot numbers are printed on each box and device)
- Whenever a new shipment of test kits is received
- If the temperature of the test kit storage area falls outside of the specific temperature requirements of the kits, usually 8 to 27°C (46 to 80°F)
- If the temperature of the testing area falls outside of the specific temperature requirements of the kits, usually 15 to 30°C (59 to 86°F). This may include testing at outreach locations.
- At periodic intervals as dictated by the user facility

The kit controls verify that the rapid HIV test is working properly and that users can properly administer and interpret the test. If the results of any one of the control tests do not match the expected result, rerun all controls using a new testing device. The control failure should be documented on the Corrective Actions Log, as well as the actions taken to resolve the issue. If the repeated control test run produces unexpected results, do not use any tests from that entire lot number and notify the Rapid Test Coordinator immediately. All results from control tests are to be documented in appropriate logs.

Also, each rapid test device contains a built-in control feature that demonstrates assay validity. A reddish-purple control line should appear in the area labeled “C”. The control line must appear for the respective test to be valid, whether the sample is reactive or non-reactive.

Test results are considered “invalid” when:

- No reddish-purple line appears next to the area labeled “C” or “Control”
- A red background in the result window makes it difficult to read the result
- If any of the lines are not inside the appropriate control or test line areas

## Required Submission/Documentation of HIV/STD Testing Activities

Documents/logs pertaining to registration, staff training, temperature storage, temperature during kit usage, results logs, and file storing safety should always be created and easily accessible to staff. Below is a list of documents that should be kept up to date and submitted when required.

Completed “Evaluation Web HIV Testing Data Form – NORTH CAROLINA” (HIV Testing Data Form), temperature logs, and results logs must be maintained in accordance to your agency’s internal records retention policy.

The following is a description of all documentation that must be completed and maintained and/or submitted along with the submission timeline where applicable.

Submissions:

- Data-entry into Luther Consulting’s EvaluationWeb (Eval Web) database
  - All agencies are required to enter testing data at least WEEKLY into Eval Web, an online platform managed by Luther Consulting (CDC contractor). Prior to accessing/entering data in Eval Web, each staff person who will use Eval Web must be “e-authenticated” through CDC’s SAMS. More information on the “e-authentication” process can be found on [page 20](#) of this manual.
  - An HIV Testing Data Form should be completed for each test event. A test event is defined as the test/s performed on one person typically at one point in time. The HIV Testing Data form captures HIV rapid and blood testing, hepatitis C rapid and blood testing, syphilis rapid and blood testing, along with gonorrhea and chlamydia testing. The HIV Testing Data Form mimics the data entry screens in Eval Web.
  - Agencies are responsible to enter test events that have HIV results of negative or invalid, and test events that do not involve HIV testing. Test events with HIV results of positive, preliminary positive, discordant, or inconclusive must be mailed to the Prevention Data Manager (double envelope a copy of the completed HIV Testing Data Form and mail it to the Prevention Program). Additional details are available in the “Eval Web HIV Testing Data Form Procedure” document.
  - As of 1/1/19 all rapid testing is reported only through Eval Web. Rapid HIV testing should no longer be reported on the SLPH form, that form is reserved solely for submitting blood samples to the SLPH for HIV and/or Hepatitis C testing. The most recent version of the HIV Testing Data Form can be found in the back of this manual on [pages 48-50](#).
  - The Prevention Program Data Team advises every agency to enter data into Eval Web at least weekly. Eval Web data entry must be completed for the prior month by the end of the

following month. For example, all of July's Eval Web testing information must be entered in Eval Web by the end of August of that same year.

- Quarterly Reports
  - All agencies who participate in the Rapid Testing program are also required to complete and submit Quarterly Reports on their rapid testing program. Please reach out to the Prevention Program Data Team or the Rapid Testing Program Team to request the template and instructions for the Quarterly Report. Additionally, agencies are required to complete the monthly inventory log located on [page 63](#).
- Rapid Testing Kit Storage Temperature Log
  - All agencies are required to document temperatures in the storage room where test kits are located. Temperatures must be recorded weekly. These logs should be maintained in agency files and may be requested by the Rapid Testing Coordinator at any time. An example of this log can be found on [page 58](#).
- Control Storage Temperature Log
  - All agencies are required to document temperatures in the storage area (refrigerator) where controls are located. Temperatures must be recorded daily. These logs should be maintained in the storage area and in agency files. These logs may be requested by the Rapid Testing Coordinator at any time (log located on [page 59](#)).
- Rapid Testing Kit Results Log
  - All agencies are required to document test results including invalid and reactive results. These logs should be maintained in agency files. An example of this log can be found on [page 60](#).
- Control Results Log
  - All agencies are required to document control tests run at the testing site. These results must be logged on the control results log and maintained in agency files. An example of this log can be found on [page 61](#).
- Inventory Log
  - All agencies are required to document the number of rapid test kits and each brand that is in stock, how many controls are in stock, and the expiration dates of each. These logs should be maintained in the storage area and in agency files. These logs will be requested by the Monitor only when they arrive for a site visit. DO NOT email the Rapid Testing Team your updated logs. An example of this log can be found on [page 63](#).
- Registration Forms
  - All agencies must have a patient registration process in place that ensures confidentiality (i.e. ID numbers).
- Confidentiality Agreements
  - All agency staff and volunteers must require a signed annual confidentiality agreement on file at the testing agency.
- Trainings Records Form

- All counselors must attend approved counseling, testing and referral training, rapid test kit training, and blood borne pathogens/universal precautions training. Staff and volunteers conducting rapid testing and prevention counseling activities are required to be skilled in client-centered counseling, safe work habits, collecting and processing rapid HIV test specimens accurately, and completing forms correctly. Skills and knowledge must be reinforced with participation in ongoing training and evaluation activities. Certificates must be stored in agency files and may be requested by the Rapid Testing Coordinator. Example is found on [page 62](#).
- Other Testing Policies
  - Agencies may have additional quality assurance measures in place with required staff compliance. Policies may be more specific than the state quality assurance plan but must meet the minimum requirements as described.

### Proficiency Testing for Staff

Proficiency testing is a mandatory part of the state rapid HIV testing program under state law *10A NCAC 42D .0101, Certification for Laboratories Conducting HIV Testing*. It ensures that testing agencies are performing the test accurately and can interpret results correctly. The Rapid Testing Coordinator may request the results of proficiency testing as a part of program evaluation. This is an annual occurrence that each NC DHHS rapid testing agency is required to obtain at their expense.

There are different options to choose from when it comes to proficiency testing. You may choose to enroll in a specific proficiency testing program. If you do not enroll in a Proficiency Testing Program, you can create your agency's own proficiency testing plan and maintain specific protocols to be reviewed by the Rapid Testing Team.

New agencies that have been accepted into the Rapid Testing Program will be expected to enact a proficiency testing program within two years of testing. See the following options:

1. Enroll in an official laboratory proficiency testing program such as the Wisconsin State Laboratory of Hygiene.

The WSLH offers three samples sent twice a year for Anti-HIV Waived Methods (HVC) and offers 5 samples sent twice a year for hepatitis (YB) and syphilis serology (SS). More information is listed below. Participants should register by December 1 of the prior year for the next year's shipping cycle. Forms, catalogs, and further information are available at this link: <http://www.slh.wisc.edu/proficiency/clinical-pt-catalog-and-ordering/>. If you would like to get in contact with the lab directly you can email [PTService@slh.wisc.edu](mailto:PTService@slh.wisc.edu) or call 1-800-462-5261.

The WSLH has also agreed to offer a 10% discount for any new lab that enrolls as part of the North Carolina Department of Health and Human Services Group. In order to receive the discount for the calendar year, labs must enter: **NC DHHS DISCOUNT** in the "Order comments" box just before the Order Total section on the enrollment form. Locations that are already the State's current customer this year should be receiving Re-enrollment paperwork that needs to be reviewed, list any changes needed, and turned back in to enroll again for future years. Any of these sites that already have that discount applied will continue receiving the discount.

Please contact the Rapid Testing Coordinator to ensure receipt of this discount.

Any site enrolling with WSLH will also be assessed a \$75 annual processing fee. The WSLH does provide the option of ordering a binder for \$15 to store PT records/reports. Payment Methods can be with Purchase Order Number (entered on the enrollment form) or you will be invoiced (can pay by VISA/MC or check). We suggest enrollments are turned in by December 1<sup>st</sup>.

Agencies new to the WSLH Proficiency Program must fill out the online Enrollment Form (link below). If an agency has used the WSLH as the chosen proficiency program in the past, please include the WSLH PT ID on this form linked here:

<http://www.slh.wisc.edu/proficiency/forms/new-customer-proficiency-testing-enrollment-form/>

Those who are current customers should receive re-enrollment paperwork to be reviewed, list changes needed, and turned back in to enroll again. Any of these sites that already have that discount applied will continue receiving the discount. Approximate shipment dates are early February and early June.

Those using the Alere Determine kit would select the HIV Ag/Ab Combo (HVC) item, and those using OraQuick HIV (waived) or INSTI (waived) can select the HIV Waived Methods (HVW) item. Anyone using the Syphilis Health Check (waived) would select the Syphilis Serology (SS) item and those using the OraQuick HCV would select the Hepatitis program. Again, the Hepatitis PT04190 would be for those reporting HIV Waived (HVW) or no HIV at all. The PT04195 would be for those that order the HIV Ag/Ab Combo (HVC) 5 sample program as well.

### **Wisconsin State Laboratory of Hygiene Program Information and Pricing**

#### Anti-HIV Waived Methods (HVW)

3 samples, 2 shipments per year

Item# PT04040

\$188 for the year

Compatible with rapid waived kits such as OraQuick and bioLytical INSTI

#### Hepatitis (YB)

5 samples, 3 shipments per year

Item# PT04190 – if ordering alone or with HVW and/or SS

\$372

Item# PT04195 – can only order this item as add-on if you also order HV or HVC

\$144 - Compatible with OraQuick HCV rapid antibody test

#### Syphilis Serology (SS)

5 samples, 3 shipments per year

Item# PT04270

\$189

Compatible with the Syphilis Health Check rapid kit (Treponemal detection)

2. Run controls every 3 months to ensure that testing staff are correctly reading test kits. Ensure staff run controls every three months on each brand of rapid test that is utilized by the testing agency.

3. Adapt your agency's own proficiency testing plan to your agency. If your agency participates in an alternative program, check with a Rapid Testing Coordinator for compliance. Ensure that specific material for rapid HIV testing proficiency is ordered.

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## POLICIES AND PROCEDURES

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To ensure adequate and consistent performance and service from your staff, guidance documents that envelope these key procedural aspects listed below should be created and easily accessible to staff for reference during training and in everyday practice. These key aspects include, dissemination of Prevention Program updates, risk behavior assessment, confirmatory testing, process for referrals, process for contacting DIS, incentive procedures, field safety for outreach and testing activities, and CTR training.

### **Dissemination of NC DHHS HIV Prevention Program Updates**

All agency staff should be kept abreast of pertinent information involving changes to the Rapid Testing Program, including key training dates, new materials, and new state testing requirements. A staff member (i.e. program manager or program coordinator) needs to be designated as a disseminator of information for testing staff.

### **Risk Behavior Assessment Guidance and Forms**

As a part of your risk behavior assessment/pretest counseling intake form, we suggest you include a portion that is a self (client) administered questionnaire to determine risk behaviors. More information can be found on [page 37](#).

Example questions include: “How often do you wear a condom?” or “Who do you have sex with...men, women or both?”

### **Confirmatory Testing for Preliminary Positives**

Mentioned in the application check list, a confirmatory plan is important for an agency pinpoint before testing in the community and in community/clinical settings. A follow up to a preliminary positive test should include either “dual protocol” or a venipuncture whole blood sample. An agency should also have a plan for reporting a positive HIV/HCV/syphilis test to either a local DIS (Disease Intervention Specialist) network, to the local health department, or to the State Laboratory of Public Health.

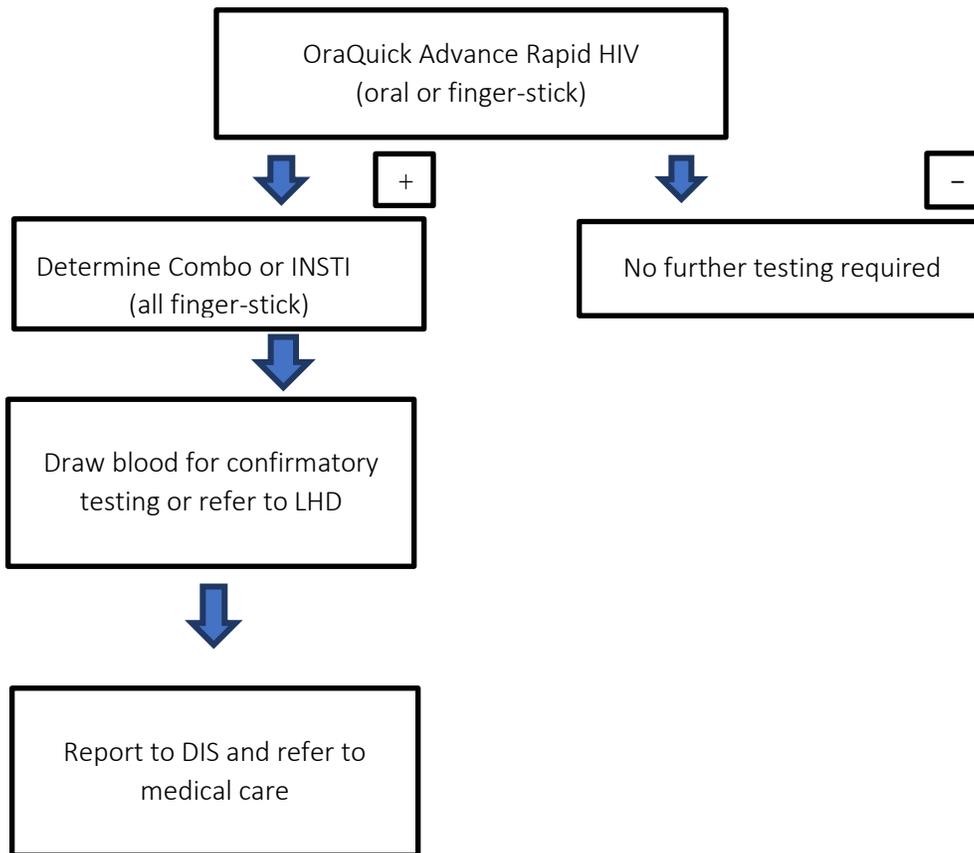
### **Dual Rapid Algorithm (Preliminary Positive OraQuick Advance HIV Rapid Test)**

The dual rapid algorithm allows for early referral to care for rapid positives. A repeatedly positive HIV antibody test meets the case definition for HIV infection. Clients testing positive on two different rapid testing kits may be considered for linkage to care and is reportable to DIS as case positive. Agencies should communicate with their linkage partners to ensure that the algorithm is acceptable for entrance into care.

Agencies may start with any of the state supplied rapid testing kits. The second rapid test must be a finger-stick specimen of a different brand of test kit. The example below starts with OraQuick Advance.

An example of a proper Dual Rapid Algorithm is outlined on the next page.

### Example Dual Protocol Process



### **Process for Referrals**

Each client has individual needs, and sometimes a client's needs that are separate from disease intervention should be addressed first. Examples include food security, housing security, prenatal medical attention, and chronic medical concerns. Individual risk assessment should aid in carving a path towards correctly referring a client not only towards HIV/HCV clinical needs, but also towards other assistance programs accessible to the client.

### **Process for Contacting/Utilizing Disease Intervention Specialists (DIS)**

Disease Intervention Specialists need to be contacted once an HIV result has been confirmed positive. They will aid in ensuring that confidential partner notification and follow-up counseling are completed.

### **Incentive Procedures**

Some agencies provide incentives for those that come in to get tested (i.e., bus passes, gift cards).

## **Field Safety for Outreach and Testing Activities**

Testing and counseling in the field is necessary for disease intervention, but also includes a certain amount of risk. Field tester safety guidelines should be highlighted, documented, and enforced.

## **Counseling, Testing, and Referral Training (CTR)**

Counselors are required to be skilled in client-centered counseling. Additionally, counselors must be knowledgeable of a wide variety of risk/harm reduction activities and be comfortable demonstrating risk/harm reduction skills such as providing condom demonstrations. Agencies supported to conduct this intervention are responsible for screening potential counselors and reinforcing skills and knowledge with internal training activities.

CTR training is not required for testing in clinical settings (i.e., substance abuse clinics, community health centers, etc.). State funded agencies that receive rapid testing kits must send all non-clinical staff to Whetstone Consultations for CTR training. State supported rapid testing agencies may attend Whetstone Consultations or conduct approved internal CTR training. Licensed practical nurses may not attend Whetstone Consultations nor give post-test counseling.

If possible, clients should only see one counselor. Consistency of the client and counselor relationship helps the client feel secure, reduces misunderstanding, and promotes the likelihood of effective risk/harm reduction. If a different counselor must provide follow-up prevention counseling sessions, careful record keeping is recommended to ensure high-quality counseling.

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## REPORTING INSTRUCTIONS

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The Division of Public Health Communicable Disease Branch received new CDC Funding Cycle (PS18-1802) beginning in 2018. This is the first time HIV Prevention and HIV Surveillance funding has been combined in a CDC grant. New HIV testing data requirements include new questions on PrEP and other essential support services, documentation of STD testing, and more data requirements associated with HIV care.

- As of 1/1/19 all agencies are required to enter data directly into Evaluation Web, an online platform managed by Luther Consulting (contractor with CDC).
- A data collection form has been created for use in North Carolina, which mirrors data entry in Eval Web. Eval Web captures HIV rapid and blood testing, hepatitis C rapid and blood testing, syphilis rapid and blood testing, along with gonorrhea and chlamydia testing. No other rapid testing reporting forms are needed as of 1/1/19.
- Eval Web provides easy access to agency data and reporting capability.

Quarterly Reports will also be required to be submitted.

### **Eval Web Requirements**

Each agency should identify at least 2 staff to become Eval Web users. A new user's contact information (name as it appears on photo ID, phone number, email, agency name and address) must be sent to both the Rapid Testing Program team and the Prevention Data Manager Meghan Furnari ([Meghan.furnari@dhhs.nc.gov](mailto: Meghan.furnari@dhhs.nc.gov)) via email with the request to gain access to Eval Web. All Eval Web users must complete the e-authentication process through CDC's Secure Access Management Services (SAMS).

The e-authentication process does take time and is comprised of several parts:

1. Send the request to become an Eval Web user to the Rapid Testing Program team and the Prevention Data Manager.
2. The Prevention Data Manager will share the contact information with CDC's SAMS.
3. The future Eval Web user will then receive an email from [SAMS\\_No\\_Reply@CDC.gov](mailto: SAMS_No_Reply@CDC.gov) with the subject "CDC: SAMS Partner Portal – Identity Verification Request Form". This email is the application that must be completed.
4. The email/application must be printed, completed, and notarized along with copies of 2 photo ID's (further details are in the email).
5. Once the completed application has been notarized the ideal way to submit the paperwork to SAMS is to scan it along with the copies of 2 photo ID's and upload that to SAMS.
6. When your documentation has been successfully delivered to SAMS you will receive an email indicating your e-authentication process has begun.
7. You will be sent an email once authorization is complete also.
8. Once e-authenticated you will be contacted by Luther Consulting regarding accessing Eval Web.

There are several training resources available to Eval Web users on the Luther Consulting Eval Web Help page. There is also a webinar recorded by the NC Data Team that is available for viewing at any time. Please

email the Prevention Data Manager, Meghan Furnari ([Meghan.furnari@dhhs.nc.gov](mailto:Meghan.furnari@dhhs.nc.gov)), to request a link to the most recent version.

### **Data Collection and Entry**

The “Evaluation Web HIV Testing Data Form – NORTH CAROLINA” (HIV Testing Data Form) is a helpful tool and mimics the data entry screens in Eval Web. The full HIV Testing Data Form can be found on [pages 48-50](#).

Please complete one HIV Testing Data Form for each client tested using a rapid HIV, and/or rapid Syphilis, and/or Rapid Hepatitis C test kit provided by the Prevention Rapid Testing Program. Be sure to include coinfection test results with the HIV test result when applicable. These include Hepatitis C, Syphilis, Gonorrhea, and Chlamydia testing.

The HIV Testing Data Form does include client name and date of birth, as this information is necessary for the verification of positive, preliminary positive, discordant, and inconclusive HIV results (see the “Eval Web HIV Testing Data Form Procedure” document and HIV Testing Data Form for details on [pages 48-54](#)).

All test events with HIV results of positive, preliminary positive, discordant, and inconclusive are required to be sent to the Prevention Program Data Team, according to the instructions in the “Eval Web HIV Testing Data Form Procedures” document on pages 51-54. Double envelope a photocopy of the completed HIV Testing Data Form/s and mail it/them to the Prevention Data Manager. Please mail the copies as soon as they are complete, and please do not enter these test events into Eval Web as the Prevention Program Data Team will do that for you. Please note that all agencies are responsible for data entry into Eval Web for test events with HIV results of negative and invalid and test events that do not involve HIV testing and should do so by the deadline of the month prior’s test events by the last business day of the following month. For example, January’s test events must be entered into Eval Web by the last business day of February.

Eval Web does not allow any identifiable information to be entered into a test event, such as names (whole name, partial name, initials) or dates of birth (except for the Client Year as it is a required data entry field). As previously mentioned, the HIV Testing Data Form includes name and DOB.

### **Data entry into Eval Web should be done at least weekly.**

Contact the Rapid Testing Program team and the Prevention Program Data Team by phone or by email (see contact information at the end of this document).

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## ANNUAL TRAINING AND TRAINING RESOURCES

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### Rapid Test Trainings

#### All Brand Rapid Test Trainings:

the NC DHHS HIV Prevention Program provides an “All Brands Rapid Test Training” on an annual basis. This is a great opportunity for State funded and State supported rapid testing agencies who are looking to have their staff trained in all rapid testing technologies that the State offers. These trainings usually take place one to two days and are the most efficient way to certify and recertify testing employees.

#### Regional Based Trainings:

Can't make it to one of the All Brand Rapid Testing Training? Have one particular brand that you need your staff trained in? Each agency is able to request on site brand specific training through one of the below brand representatives. A Rapid Testing Monitor can assist you with site scheduling. The Rapid Testing Team asks that you bring at least 10 attendees to an onsite training in which a brand representative is traveling for. You may partner with other nearby rapid testing agencies that also need staff trained in the specific rapid testing technology. You may request this through one of the Rapid Testing Coordinators or request this training directly through one of the representatives mentioned below. **If you request directly, you must inform a Rapid Testing Coordinator.**

#### Web-Based Trainings:

You can contact any of the representatives mentioned below to offer a web-based training to you and your staff in the wake of COVID-19 restrictions.

#### OraSure Technologies

Heather Bronson, Public Health Account Manager

HBronson@orasure.com

484-241-8377

(OraQuick ADVANCE HIV Rapid HIV -1/2 Antibody Test, OraQuick HCV Rapid Antibody)

#### Abbott

Michael Culm, Strategic Business Executive, US Infectious Disease

michael.culm@abbott.com

704-249-5451

(Determine HIV ½ Ag/Ab Combo)

#### Diagnostics Direct

Jeff Tobias, Vice President-Sales and Marketing

jtobias@dd-2u.com

866-358-9282 ext. 102

(Syphilis Health Check)

#### bioLytical Laboratories Inc.

Zachary Barrentine

zbarrentine@biolytical.com

360-922-4135  
(INSTI HIV-1/ HIV-2 Rapid Antibody Test)

Before contacting any of the representatives listed below, please contact the Rapid Testing Team to ensure the most updated contact information.

### **CTR Whetstone Consultations Trainings:**

As mentioned above in earlier sections, “Counseling, Testing, and Referral” (CTR) Trainings are available to State supported agencies through Whetstone Consultations. Through a grant from HIV/STD Prevention and Care, Whetstone Consultations provides training to local health departments and community-based organizations that provide HIV counseling and testing services to their clients. For information about training objectives, registration, available dates and locations, see <https://www.whetstoneconsultations.com/>.

Whetstone trainings are free for State supported agencies. Testing agencies are responsible for providing funds concerning mileage, hotel stay, and food for their respective staff attending the training.

If Whetstone is not used for training agency staff in CTR, then another form of training must be approved by a Rapid Testing Counselor.

### **Phlebotomy Training:**

The Communicable Disease Branch has quarterly trainings in Fayetteville, NC. Agencies should contact the Rapid Testing Monitor for upcoming training dates.

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## CONSEQUENCES OF PROTOCOL VIOLATIONS

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Failure to follow North Carolina's rapid testing and prevention counseling protocol may result in a cease of rapid testing activities indefinitely or until protocol issues are resolved. Protocol violations witnessed by or reported to the Rapid Testing Coordinator will be discussed with the testing site as soon as possible. Corrective action, if any, will be documented and submitted to the testing site and the HIV Prevention Program

**An immediate halt of testing activities can occur when:**

- Confidentiality is compromised in the test processing area or through handling of documentation.
- Quality assurance records/documents are not maintained as specified in this protocol.
- The agency fails proficiency testing.
- Informed consent is not obtained from clients prior to specimen collection.
- Completed HIV Test forms are not stored in a confidential manner and the specified copies are not submitted at frequent intervals
- Rapid test kits or other testing supplies are distributed to and/or used by unauthorized entities or are unaccounted for.
- The agency's CLIA waiver or HIV license expires without intent to renew.
- Confirmatory testing is not offered/referred to a client who has a preliminary positive rapid test result.
- There is failure to submit monthly Eval Web documentation by the end of the following month.
- Documentation for clients who test positive or inconclusive or discordant for HIV is not filled out completely and accurately and is not mailed to the Data Team **(Positive/Inconclusive/Discordant HIV tests must be reported to the Prevention Data Team by mailing a copy of the completed HIV Testing Data Form).**
- Clients who test positive for HIV are not linked to appropriate HIV medical treatment services and/or follow-up on HIV medical care linkages are not made and/or documented.
- Data is not entered into Eval Web within 3 months of collection or no notification is sent to the Rapid Testing Coordinator.

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# REFERENCE MATERIAL

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## Self Audit: Prevention of Diversion

Community Health Centers (CH/FQ/FQHC/FQHCLANH)



**Purpose:** This tool provides a sample self-audit for community health centers (CH/FQ/FQHC/FQHCLANH) to comply with 340B requirements regarding the prevention of diversion.

**Background:** Section 340B of the PHS Act prohibits diversion – the resale or other transfer of a 340B drug to ineligible patients. To adhere to this requirement, a covered entity is responsible for the tracking and accountability of its 340B drugs to ensure that diversion has not occurred.

**This self-audit tool is part of a series focusing on three compliance elements:**

1. Eligibility
2. Prevention of Diversion
3. Prevention of Duplicate Discounts

Prior to completing the Eligibility Self-Audit Tool, covered entities are encouraged to:

- Map their 340B drug universe (this tool is available in [Word](#) and [Excel](#))
- Complete the [Covered Entity Self Audit: Policy and Procedure](#).

**Instructions:** Covered entities should complete this tool at least quarterly, however exact parameters should be adjusted to meet entity-specific auditing needs.

The following data points are used to complete this tool:

- 1) Identify and collect relevant data for the most recent 3-month period, as follows:
  - a. List of eligible covered entity locations (clinics/departments/service units including main site and associated sites registered on 340B OPAIS)
  - b. List of eligible providers
  - c. Proof of provider eligibility (contract/employment records, referral for consultation)
  - d. Patients' health care records
  - e. 340B dispensing records
  - f. 340B purchasing invoices
  - g. NDC crosswalk (for virtual inventory)
  - h. Accumulation report (for virtual inventory)
  - i. Inventory report (for physical inventory)
- 2) Audit samples.
  - a. Select 20 invoices from 340B purchases, as follows: 10 invoices with the highest volume (number of lines) and 10 invoices with the highest total cost
  - b. Randomly select 20 different drugs from the 340B purchasing invoices identified in step 2a (recommend one per invoice)
  - c. Randomly select one 340B dispense/administration for each of the 20 drugs from step 2b
- 3) Randomly select 1 day of accumulations from the accumulation report





Table 1 Assessment Questions	Yes	No	N/A	Unsure
<p><b>1) Did each of the administered/dispensed 340B drugs tested in Table 1 originate from an eligible location?</b> <i>(An eligible clinic includes the main health center or an outpatient off-site location included in the scope of grant or FQHC-LA designation.)</i></p> <p>Answer "Yes" to the question only if all answers are YES the column 3, "340B eligible location," in Table 1.</p> <p><i>If response is "No" or "Unsure," explain: (Identify and discuss each outlier)</i></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p><b>2) Did each of the administered/dispensed 340B drugs tested in Table 1 originate from an eligible location registered on the entity's 340B OPAIS record?</b> <i>(The eligible clinic location is registered on 340B OPAIS as the main health center or associated site. Sites must be operational in the HRSA Electronic Handbook prior to being registered in 340B OPAIS.)</i></p> <p>Answer "Yes" to the question only if all answers are YES in column 4, "Location with 340B ID," in Table 1.</p> <p><i>If response is "No" or "Unsure," explain: (Identify and discuss each outlier)</i></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p><b>3) For each administered/dispensed 340B drug tested in Table 1, was the drug dispensed/administered as a result of a service included in the scope of grant or FQHC-LA designation (if applicable)?</b></p> <p>Answer "Yes" to the question only if all answers are YES in column 5, "Drug dispensed/administered as a result of a service included in the scope of grant?" in Table 1.</p> <p><i>If response is "No" or "Unsure," explain: (Identify and discuss each outlier)</i></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p><b>4) For each administered/dispensed 340B drug in Table 1, did each patient receive health care from providers who were employed or contracted by the covered entity, or provided care under other arrangements (such as a referral for consultation)?</b></p> <ul style="list-style-type: none"> <li>List providers who prescribed the drug deemed 340B eligible</li> <li>Compare this list to the entity's eligible provider list</li> <li>Identify providers who are employed or contracted</li> <li>Identify providers providing care as a result of a referral for consultations and locate a documented referral for consultation <u>and</u> a documented summary of the referral visit in the patient's medical records to justify the 340B entity had responsibility for the care</li> <li>Determine eligibility of providers</li> </ul> <p>Answer "Yes" to the question only if a YES is documented in either column 6a or 6b, "Eligible provider?" in Table 1.</p> <p><i>If response is "No" or "Unsure," explain: (Identify and discuss each outlier)</i></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<p><b>5) Were each of the administered/dispensed 340B drugs tested in Table 1 part of an episode of care documented in the patient's health care record maintained by the entity?</b> <i>(Demonstrates that the covered entity maintains responsibility for the care of the patient)</i></p> <p>Answer "Yes" to the question only if all answers are YES in column 7, "Drug and visit documented in the entity's health care record?" in Table 1.</p>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<p><i>If response is "No" or "Unsure," explain: (Identify and discuss each outlier)</i></p>	



Table 2 Assessment Questions	Yes	No	N/A	Unsure
<p>1) For each of the drugs tested in Table 2 during the defined time period, does the number of units purchased and dispensed reconcile to the number of units left in inventory?</p> <p>Answer "Yes" to the question only if all answers are YES in column 8, "Inventory units reconciled?" in Table 2.</p> <p><i>If response is "No" or "Unsure," explain: (Identify and discuss each outlier)</i></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>2) For each of the drugs tested in Table 2 during the defined time period, were all identified variances resolved and documented? (Demonstrates that variances in drugs dispensed versus purchased were not the result of diversion)</p> <p>Answer "Yes" to the question only if all answers are YES in column 9, "Variance resolved?" in Table 2.</p> <p><i>If response is "No" or "Unsure," explain: (Identify and discuss each outlier)</i></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Physical Inventory</b>				
<p>1) If using a <u>physical inventory</u> method, are the 340B drugs distinguishable from the non-340B drugs on the shelves?</p> <p>To answer this question, the reviewer will be required to visit the medication storage area(s) involved in this self-audit.</p> <p><i>If response is "No" or "Unsure," explain:</i></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



Self Audit: Prevention of Diversion  
Community Health Centers (CH/FQ/FQHC/FQHCL/NH)



Table 3 Assessment Questions	Yes	No	N/A	Unsure
<p><b>1) For each drug sample tested in Table 3, was the dispensed quantity correctly accumulated?</b></p> <p>Answer N/A if a physical inventory is used.</p> <p>Answer "Yes" to the question only if all answers are YES in column 4, "Drug NDC quantity dispensed matches quantity accumulated?" in Table 3.</p> <p><i>If response is "No" or "Unsure," explain: (Identify and discuss each outlier)</i></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p><b>2) For each drug sample tested in Table 3, did the 11-digit NDC billed match the 11-digit NDC accumulated?</b></p> <p>Answer N/A if a physical inventory is used.</p> <p>Answer "Yes" to the question only if all the answers are YES in column 5, "NDC billed matches NDC accumulated?" in Table 3.</p> <p><i>If response is "No" or "Unsure," explain: (Identify and discuss each outlier)</i></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p><b>3) For each drug sample tested in Table 3, did the drug NDC and quantity ordered on the entity's 340B account match the drug NDC and quantity deducted from the 340B accumulator?</b></p> <p>Answer N/A if a physical inventory is used.</p> <p>Answer "Yes" to the question only if all answers are YES in column 6, "Drug NDC and quantity ordered match drug NDC and quantity deducted from 340B accumulator?" in Table 3.</p> <p><i>If response is "No" or "Unsure," explain: (Identify and discuss each outlier)</i></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p><b>4) For each drug tested in Table 3, did the drug NDC and quantity received match the drug NDC and quantity ordered?</b></p> <p>Answer N/A if a physical inventory is used.</p> <p>Answer "Yes" to the question only if all the answers are YES in column 7, "Drug NDC and quantity received matches drug NDC and quantity ordered?" in Table 3.</p> <p><i>If response is "No" or "Unsure," explain: (Identify and discuss each outlier)</i></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.

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**Letter of Acknowledgement (340B Eligibility)**

DHHS Communicable Disease Branch

The purpose of this letter is to acknowledge that the Communicable Disease Branch (CDB) provides support to (Agency X) through the provision of funding or in-kind support from the Strengthening Sexually Transmitted Disease Prevention and Control for Health Departments (STD PCHD) grant (grant # 1NH25PS005152). This provision of funding or in-kind support confers eligibility for HRSA’s 340B drug pricing program. Application to and participation in the HRSA 340B program is not required. Should your agency choose to participate, please be aware that it is the responsibility of your agency to apply through HRSA and meet the requirements of becoming a 340B covered entity. Questions concerning 340B requirements should be directed to Apexus Answers (HRSA’s contracted 340B management entity) and not the Communicable Disease Branch.

In the event that your agency wishes to participate in the 340B program, you agree to register with HRSA to become a 340B covered entity within nine months of receiving STD grant funds or in kind support and will abide by all requirements set forth by HRSA’s Office of Pharmacy Affairs for the management and use of 340B funds. Signing this LOA indicates contractor acknowledgement and receipt of the 340B FAQs, the HIV Prevention Program 340B eligibility letter and Apexus Answers documents attached. It further constitutes acknowledgement that the agency is solely responsible for meeting all HRSA and Apexus requirements for 340B eligibility and maintenance.

Contractor

BY: \_\_\_\_\_  
Program Administrator

BY: \_\_\_\_\_  
Witness

DATE: \_\_\_\_\_

Department of Health and Human Services, Communicable Disease Branch

BY: \_\_\_\_\_  
Rapid Testing Program Coordinator

DATE: \_\_\_\_\_

Facts below are from Whetstone Consultations <https://www.whetstoneconsultations.com/>

## HIV Facts

- HIV is spread through Blood, Semen, Vaginal Fluids & Breast Milk. If one of these fluids is not involved in sufficient quantity to infect, then transmission will not occur. In addition, there must be a way for the fluid to get out of the body of the infected person, and into the body of an uninfected person.
- HIV is most widely spread through sexual contact and sharing needles. Transmission is affected by the fluids involved, the type of sex and the role (receptive or insertive; receiver or giver.)
- HIV disease is potentially deadly and there is no cure, but there are good treatments that can extend the length of life and improve the quality of life.
- Some physicians will not prescribe the medications for some clients (e.g. people who are homeless, persons with mental illness, etc.)
- Numerous and difficult side effects of the medications are experienced by many patients. Overall, the benefits of HIV medicines far outweigh the risk of side effects. In addition, newer HIV regimens cause fewer side effects than regimens used in the past.
- Early diagnosis and assessment by an HIV experienced physician can greatly improve the health and happiness of clients.
- The window period is the time during which a person can be infected but antibody tests will not detect infection. This varies from 3 weeks to 3 months depending on the lab test that is being performed.
- Acute HIV occurs shortly after infection (2-6 weeks) and includes symptoms like those of severe flu or mononucleosis: fever, generated aches and pains, fatigue. It may also include rashes, nausea, swollen lymph nodes, and diarrhea. During this time the viral load of the patient is high and therefore the client is highly infectious.

## Hepatitis Facts

- Hepatitis A:
  - Found in feces
  - Contracted by contaminated food
  - Getting the virus in the mouth during oral-anal contact with an infected person
  - Symptoms: Feeling tired, joint pain, sick stomach and yellowish eyes and skin
  - Vaccination: YES
- Hepatitis B:
  - Contracted by exposure to unprotected sex with an infected person or sharing needles or other drug equipment with an infected person

- Symptoms: Only about half who have HCV have symptoms which can be feeling tired, joint pain, sick stomach and yellowish eyes and skin.
- Vaccination: YES
- Hepatitis C/HCV:
  - Contracted by exposure to sharing needles or other drug equipment with an infected person
  - Rarely people get HCV from unprotected sex with an infected person
  - Symptoms: Often symptom-free at first but may eventually develop severe liver disease
  - Vaccination: NO, expensive cure

## Risk Behavior Assessment Guidance

### Assessment:

Any activity that can result in the transmission of HIV is considered a risk behavior. Example may include having sex without a condom, getting semen or vaginal fluids in your mouth, or sharing needles.

### Risk Screening:

In order to determine a client's risk to contracting HCV or HIV, an agency can choose to instruct their staff to partake in a variety of assessments.

These include:

- Self-Administered Questionnaire
- History Taking
- Conversation with the Client
- Or a combination of three

### Personalized Risk Assessment:

In order to start the counseling session, the counselor can ask, "Tell me what you know about how someone gets HIV." Make sure to determine that HIV is transmitted primarily through sex and sharing needles.

You can also include in your opening statement, "Since sex and sharing needles are the two primary ways HIV is transmitted, those are the things we have to talk about with our clients. I am going to ask some important, but personal, questions so I can understand your risks and help you keep from becoming infected."

Make sure to ask these specific questions:

- "What kind of sex do you have: oral (your mouth on someone's genitals or someone's mouth on your genitals) or vaginal (penis inserted into a vagina) or anal (penis in an anus)?"
- "What is the gender of the people you have sex with?"
- "How many people have you had sex with in the past 6 months?"
- "When was the last time you put something in your body with a needle?" or "What experience have you had with drugs and needles?" and then "How do you get high? Stoned? Altered?"

## Conducting Rapid Testing and Prevention Counseling with a Client (Pre and Post Test Counseling)

### Risk Reduction Planning

Along with a risk reduction assessment, the counselor can use the “pre” test time period to educate the client on HIV/HCV and how to reduce exposure risk.

If a client is **having sex**, then suggest that they can use condoms (if not all the time then at least sometimes) and to try and limit the number of people you have sex with. If they are **sharing needles**, ask them if they can clean them before they use them.

To do this you can ....

- Provide a brochure or show a video in a waiting room
- Verbally inform clients
- Link risk assessment to specific risk reduction strategies
- Counsel client on individualized strategies
- Offer options (some might be less likely to cause infection but do not eliminate risk)

### Goal Setting & Action Plans

- Find out what goals the client wants to adopt to directly prevent HIV/HCV transmission (ex: knowing HIV status of partners, not sharing needles)
- The counselor can help the client pinpoint specific actions that they can take to achieve this goal (ex: carrying condoms, talking openly with each partner)

### Testing

There are steps in place that you can follow leading up to the testing.

- **Explain the test** and how the specimen will be collected, how and when the test will be given, and what the test means.
- **Determine** if the client is ready to know their status.
- **Refer** a client the appropriate services. This is explained in the presentation portion of the packet
- **Develop a follow up plan** with the client so that they can receive the news of their status.

All agencies conducting the HIV Prevention Counseling and Rapid Testing intervention in North Carolina should model sessions with clients according to the format and guidelines listed below.

Before performing a rapid HIV test:

- Introduce yourself to the client. Give the client your name and welcome them to the testing site.
- Assess client’s readiness to receive the results on the same day. Ask the client questions to determine their motivation for getting tested and what, if any, support system is in place.
- Offer options for testing (oral swap, finger-stick, venipuncture, etc.) that are available at the testing site. Offer clients the choice of receiving results the same day or at a later date.
- Describe the testing process, what type of specimen will be collected, how long the whole process will take, and what each of the three possible results mean. It is a part of informed consent for clients to understand what type of specimen will be taken from them, how long the rapid testing session will take, and that the three possible results are preliminary positive,

negative, and invalid. Clients should also be informed what actions will take place after each of the results.

- Explain to client that if a preliminary positive result is received, a confirmatory test will be conducted. According to the CDC, a very important part of counseling persons who have a reactive rapid HIV test result is to make sure they understand that the test result is preliminary, and further testing must be done to confirm the result. Counselors must assess if testing is beneficial at this time based on the client's response to how they would react to getting a preliminary positive result.

Persons who have identified themselves as HIV positive should not be retested with a rapid test. Individuals infected with HIV-1 and/or HIV-2 who are prescribed antiretroviral medication can produce false negative rapid test results under some circumstances. Self-identified HIV infected persons can be offered a conventional HIV test and should be referred to case management and/or medical care.

- Address Partner Services, including that if the client tests positive, a DIS (Disease Intervention Specialist) will contact them to offer services. Emphasize that this is a free and confidential service that provide clients with help in contacting partners and other referral services.
- Offer the client a confidential test and explain what confidential testing means. Confidential testing indicates that a client is willing to provide personal identifiers that can be used to link the individual to his/her rapid HIV test result.
- Obtain Informed Consent. Informed Consent (verbal or written) for HIV testing must be obtained prior to clients receiving any HIV testing. Clients testing confidentially must provide written consent or verbal consent must documented in the client's records.
- Provide appropriate subject information pamphlet for the rapid test being conducted. The FDA requires that all test subjects receive the "Subject Information" pamphlet produced by the manufacturer of the rapid test device being used prior to collecting a specimen for testing. These pamphlets are included in each box of the test kits.
- Collect and run specimen. Testers must follow the manufacturer's instructions provided by the manufacturer of the rapid test device he/she will be using. In addition to manufacturer instructions, identifying stickers from the HIV Test form should be placed on the testing device (or on the developer solution vial for OraQuick tests) to ensure quality control. **Not following the manufacturer's instructions may result in inaccurate test results.**

While a rapid HIV test is processing:

- Identify personal risk behaviors and safer goal behaviors of the counseling process. A personalized risk assessment should explore previous risk-reduction efforts and identify successes and challenges in those efforts. Factors associated with continued risk behavior that might be important to explore include using drugs or alcohol before sexual activity, underestimating personal risk, perceiving that precautionary changes are not an accepted peer norm, perceiving limited self-efficacy for successful change efforts, receiving reinforcement for

frequent unsafe practices (e.g., a negative HIV test result after risk behaviors), and perceiving that vulnerability is associated with "luck" or "fate".

When considering safer goal behaviors, counselors should focus on reducing the client's current risk and educating about HIV transmission modes. Counselors should discuss the HIV transmission risk associated with specific behaviors or activities the clients describe and then discuss lower-risk alternatives.

For example, if clients indicate that they believe oral sex with a risky sex partner poses little or no HIV risk, the counselor can clarify that, although oral sex with an infected partner might result in lower HIV transmission risk than anal sex, oral sex is not a risk-free behavior, particularly when commonly practiced. If clients indicate that they do not need to be concerned about HIV transmission among needle-sharing partners if they use clean needles, the counselor can clarify that HIV can be transmitted through the cooker, cotton, or water used by several persons sharing drugs. With newly identified or uninformed HIV-infected clients, the counselor should discuss HIV transmission risks associated with specific sexual or drug-use activities, including those in which the client might not be currently engaged.

Although the optimal goal might be to eliminate HIV risk behaviors, small behavior changes can reduce the probability of acquiring or transmitting HIV. Behavioral risk-reduction steps should be acceptable to the client and appropriate to the client's situation. For clients with several high-risk behaviors, the counselor should help clients focus on reducing the most critical risk they are willing to commit to changing.

- Continue to assess client readiness to receive result. Counselors have until the timer goes off, thus indicating the rapid test is finished processing, to assess whether the client is ready to receive same day test results. Counselors **may not** give test results before the kit is fully resolved per the manufacturer guidelines. If the counselor leaves to interpret the test result, they must provide the result upon returning to the client.

After the rapid HIV test has developed:

- Provide the test result to the client.
- Create a client action plan, offer referrals and provide support, summarize and close
- Set up follow-up appointment for preliminary positive clients to receive confirmatory result or, if necessary, those testing negative to get retested.
- Provide condoms, other risk/harm reduction tools and appropriate literature.
- Complete the remainder of the HIV Testing Data Form, Kit Results Log and other documentation as needed.
- Correctly dispose of used testing supplies following universal precautions and safe work practices at all times.

Continue counseling session based on the results of the test:

**Preliminary Positive:**

- Accurately communicate results with client—if the result shows signs of HIV antibodies or antigen, then a confirmatory test must be done to be sure.

- Allow time for emotional response. Do not rush the client into conversation.
- Ensure the client understands what the result means and assess client concerns.
- Offer to take a confirmatory whole blood sample (using phlebotomy) or offer to test them using a second brand of HIV rapid test (in accordance with the dual protocol algorithm). Clients who have a reactive/preliminary positive rapid HIV test result must be offered a confirmatory test or second rapid test and linked to early intervention after receiving their preliminary positive result. North Carolina allows for dual rapid confirmatory algorithm to increase the efficiency of linkage to care. See [page 17](#) for the algorithm.
- Review the client's risk assessment and risk reduction plan.
- Emphasize the importance in taking the same health precautions as a person who may have a confirmed HIV positive test result. HIV positive clients must be informed about control measures under state law 10A NCAC 41A .0202, *Control Measures—HIV*.
- Negotiate additional referrals with client, including potential medical and partner services.
- Set appointment to return for confirmatory blood draw test results.
- Provide condoms and literature as deemed appropriate.
- Document the result on the HIV Testing Data Form and Kit Results Log

**Negative:**

- Review with the client his/her risk assessment and risk reduction plan. Discuss plans for staying negative.
- Assess the need to retest.
- Provide condoms and other risk/harm reduction tools and appropriate literature.
- Assess the client's need for other referrals.
- Make sure client understands the window period and whether he/she needs to be retested at a later date.
- Document the result on the HIV Testing Data Form and Kit Results Log

**Invalid:**

- Explain that there was a problem running the test, either related to the test device or the specimen collected.
- Assess client concerns and emotional response.
- Assure client that quality assurance procedures are in place. **NOTE: If you have not personally checked all storage logs that day, do so before retesting.**
- Collect new specimen and run it with new rapid test device or conduct a conventional test if the client refuses an additional rapid test.
- Provide condoms, other risk/harm reduction tools and appropriate literature.
- Review the client's risk assessment and risk reduction plan. Emphasize the need to take the same risk reduction precautions as established.
- Document the invalid result on the Kit Results Logs. Document the repeated rapid test result on the HIV Testing Data Form and Kit Results Log.

**Confirmatory HIV Testing**

Following a preliminary positive rapid test, the client must be administered a confirmatory HIV test. This can be done with a second rapid test or a blood draw.

**Negative or Indeterminate (therefore Discordant Result):**

- The client should be told that their HIV status is not certain at this point and further testing is needed.
- Explain that this is a discordant result. Do not use the terms “false positive” or “false negative” as these are not appropriate descriptions of this situation.
- Assess client’s concerns.
- Client should be given an appointment to return for retesting in 2 weeks. It is highly recommended and compliant with CDC rapid testing protocol that follow-up confirmatory testing be conducted with a new specimen whenever possible.
- Review the client’s risk assessment and risk reduction plan.
- Provide condoms, other risk/harm reduction tools and appropriate literature.
- Document the result on the HIV Testing Data Form and Kit Results Log and Corrective Actions Log. The Rapid Testing Coordinator should be notified as soon as possible of discordant results.
  - A copy of the completed HIV Testing Data Form with discordant results must be mailed (double envelope) to the Prevention Program Data Team. Do not enter a test event with a result of HIV discordant into Eval Web, as the Prevention Program Data Team will do that for you.

**Positive:**

- Allow time for an emotional response. Do not rush the client into a conversation.
- Ensure client understands what test result means.
- Make client aware of need for medical evaluation and the availability of treatment.
- Provide linkage to care. Linkage to care links newly identified HIV-infected persons, not currently in care, to a primary care provider. The counselor also educates basic facts about HIV and may link clients to other services when barriers are identified.
- Reassess the client's risk for transmitting HIV infection to others. Discuss partner counseling options and discuss the client's plan to inform his/her partners.
- Assist client in identifying necessary linkages. Make appropriate connections and set appointments.
- If working with a positive woman who is pregnant and not in prenatal care, link the client to prenatal care.
- Provide condoms and appropriate literature.
- Inform DIS. Clients are to be informed of the importance of contacting sex and/or needle sharing partners. Counselors should record clients’ full contact information on the appropriate areas of HIV Testing Data Form facilitate referral follow up, partner services, and surveillance. Counselors must discuss the North Carolina public health policy that provides for DIS to contact all persons testing reactive to HIV to discuss and offer partner services.
- After 30 days if linkages cannot be confirmed, make appropriate documentation in client’s patient information and document the result on the Kit Results Logs.
- Once the HIV Testing Data Form is complete, mail a copy of the form (double envelope) to the Prevention Program Data Team. Do not enter a test event with a result of HIV Positive into Eval Web, as the Prevention Program Data Team will do that for you.

## NC Rapid HIV/HCV/Syphilis Testing Program Enrollment Requirements

This document outlines the enrollment requirements for the Rapid Testing Program. Please complete all sections and return to the Rapid Test Coordinator. For questions, contact Carlotta McNeill at the Communicable Disease Branch at 919-755-3144 or [Carlotta.Mcneill@dhhs.nc.gov](mailto:Carlotta.Mcneill@dhhs.nc.gov).

<b>1. Contact Information</b>	
Agency Name:	
Contact Person:	Title:
Mailing Address (No P.O. Box):	
City, State, Zip Code:	
Shipping Address (if different than mailing):	
Phone Number:	Fax:
Email Address:	

<b>2. CLIA Certificate of Waiver Number and HIV Testing License Number</b>
<i>Indicate your CLIA Certificate of Waiver and HIV Testing License numbers below. To apply, contact the Division of Health Service Regulation, <a href="https://info.ncdhhs.gov/dhsr/ahc/clia/">https://info.ncdhhs.gov/dhsr/ahc/clia/</a> or <a href="mailto:azzie.conley@dhhs.nc.gov">azzie.conley@dhhs.nc.gov</a>, 919-855-4620.</i>
CLIA Certificate of Waiver Number:
HIV Testing License Number:

<b>3. Medical Provider</b>
List the name of the medical provider who will be responsible for your agency's standing orders.
Name:
Office Phone Number:
Address:

<b>4. Confirmation of Positive Results</b>
How will your agency confirm a preliminary positive result, i.e., draw blood, dual rapid test, referral to LHD or DIS? <b>Please indicate if you need assistance with this process.</b>

<b>5. Referral Network</b>
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Post Approval Expectations:

Within 3 months of application approval, the newly accepted rapid testing program is expected to:

1. Create a Quality Assurance (QA) Plan
  - Agency must have rapid HIV testing policies, procedures, and QA plan that are consistent with State policies. QA plan must include records management protocols such as test run logs, control log, temperature logs, and storage logs. It must also include the testing protocol and use of test and control kits. State QA plan and associated documents is provided in the supplementary documents of this enrollment packet, and is also found on the website: <http://epi.publichealth.nc.gov/cd/stds/programs/testing.html>.
2. Plan for staff training and update training logs
  - Required trainings include Whetstone Trainings (pre- and post-test counseling), brand specific rapid testing trainings, and phlebotomy training.
3. Create a confidentiality policy
  - Agency must have a confidentiality policy that includes the agency's rapid HIV testing confidentiality policies and procedures that address informed consent, legal and ethical policies, client confidentiality, and data security. These policies must be signed on an annual basis.

**STATE OF NORTH CAROLINA**

**HIV Testing Certification**

**Initial/Renewal Application**



Complete form to APPLY for or to RENEW Certification for HIV testing. Complete one application form for each HIV testing site location.

**CERTIFICATION FOR HIV TESTING**

RENEW  NEW (FOR OFFICE USE ONLY) DATE CERTIFICATE MAILED: \_\_\_\_\_

Name \_\_\_\_\_ CERTIFICATE # \_\_\_\_\_

DBA (if different from above) \_\_\_\_\_

Site LOCATION \_\_\_\_\_

CITY \_\_\_\_\_ State \_\_\_\_\_ ZIP \_\_\_\_\_

MAILING ADDRESS (if different from site) \_\_\_\_\_

PHONE \_\_\_\_\_ EIN# \_\_\_\_\_ Medicare # \_\_\_\_\_

OWNED by \_\_\_\_\_

Name/Title of Director \_\_\_\_\_

**COMPLETE AS APPLICABLE**

HIV Confirmatory Test(s) performed  Name: \_\_\_\_\_

HIV Proficiency Testing Program \_\_\_\_\_

CLIA ID# \_\_\_\_\_ Expires \_\_\_\_\_

AABB ID# \_\_\_\_\_ Expires \_\_\_\_\_

JCAHO ID# \_\_\_\_\_ Expires \_\_\_\_\_

CAP ID# \_\_\_\_\_ Expires \_\_\_\_\_

CONTACT PERSON \_\_\_\_\_ TITLE \_\_\_\_\_ PHONE \_\_\_\_\_

AUTHORIZED SIGNATURE \_\_\_\_\_ TITLE \_\_\_\_\_ DATE \_\_\_\_\_

Please return to: Acute Care/CLIA  
Certification Section 2713  
Mail Service Center Raleigh  
NC 27699-2713

## Registration and Renewal Process for Providers of HIV Testing, PAP Smear Screening & Mammography Screening

This is a registration process for identification of facilities in NC providing these services.

- A certificate is issued every two years.
- Certificates expire on December 31st.
- Certificates are printed and mailed to facilities along with appropriate letter.
- There is no fee at this time for this certificate.
- All are renewed at the same time regardless of application date.
- Initial applications received during the year will have the same expiration date for that certification period.
- Completed applications can also be faxed to 919-733-0176; It is not necessary to send them in the mail.



**3 Negative Test Result**  
(complete for ALL persons at time of testing)

Is the client at risk for HIV infection?  
 No  Yes  Risk Not Known  Not Assessed

Client screened for PrEP eligibility?  No  Yes

Is the client eligible for PrEP referral?  
 No/Not Asked  Yes, CDC criteria  Yes, Local criteria

Was the client given a referral to a PrEP provider?  
 No/Not Asked/Not Eligible  Yes

Was the client provided with services to assist with linkage to a PrEP provider?  
 No/Not Asked/Not Eligible  Yes (only for Regional PrEP Coordinators)

**4 Positive Test Result**  
(complete for persons testing POSITIVE for HIV)

Did the client attend an HIV medical care appointment after this positive test?  
 Yes, confirmed  No  Yes, self-report  Don't Know  
 If Yes, Date: / /

Has client ever had a positive HIV test?  
 No  Yes  Don't Know  
 If Yes, Date: / /

Client provided with behavioral risk-reduction counseling?  
 No  Yes

Client contact info to Health Dept for DIS/Partner Services?  
 No  Yes

Client's most severe housing status in the last 12 months?  
 Literally homeless  Not asked  
 Unstably housed or at risk of losing housing  Declined to Answer  
 Stably housed  Don't know

If the client is female, is she pregnant?  
 No  Yes  Don't know  Declined to Answer

If YES → Is the client in prenatal care?  
 No  Don't know  Declined to answer  
 Yes  Not asked

Screened for need of perinatal HIV services?  
 No  Yes

Need identified for perinatal HIV services?  
 No/Not Asked  Yes

Was the client referred for perinatal HIV services?  
 No/Not Asked/Not Needed  Yes

**5 Additional Tests**  
(complete for all persons)

Client tested for any co-infections?  No  Yes

SYPHILIS Tested?  No  Yes *If Rapid → Local Use Field 2*  
 Result:  Reactive/New Infection  
 Not Infected  Don't Know

GONORRHEA Tested?  No  Yes  
 Result:  Positive  Negative  Don't Know

CHLAMYDIAL INFECTION Tested?  No  Yes  
 Result:  Positive  Negative  Don't Know

HEPATITIS C Tested?  No  Yes *If Rapid → Local Use Field 3*  
 Result:  Positive  Negative  Don't Know

**6 PrEP Awareness & Priority Populations**  
(complete for all persons)

Has client ever heard of PrEP?  No  Yes

Is client currently taking PrEP medication?  No  Yes

Has client used PrEP in the last 12 months?  No  Yes

Sex with Male (past 5 yrs)?  No  Yes

Sex with Female (past 5 yrs)?  No  Yes

Sex with Transgender Person (past 5 yrs)?  No  Yes

Inject Drugs/Substances (past 5 yrs)?  No  Yes

**7 Essential Support Services**  
(complete as indicated, please answer each question)

	Screened for need	Need found	Provided or referred
<i>Complete for clients testing HIV-Positive only</i>			
Navigation services for linkage to HIV medical care	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
Linkage services to HIV medical care	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
Medication adherence support	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<i>Complete for ALL tested Clients</i>			
Health benefits navigation and enrollment	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
Evidence-based risk-reduction intervention	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
Behavioral Health Services	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
Social Services	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes

<b>8 Local Use Fields</b>
Local Use Field 1 – <i>If POC/Rapid test(s) AND a Laboratory-based test were performed, enter RHIV</i>
Local Use Field 2 – <i>If Syphilis POC/Rapid test was performed, enter RSYPH</i>
Local Use Field 3 – <i>If Hepatitis C POC/Rapid test was performed, enter RHCV</i>
Local Use Field 4 – <i>PREP Coordinators Use Only, number of appts</i>
Local Use Field 5
Local Use Field 6
Local Use Field 7
Local Use Field 8

**Value Definitions for POC/Rapid Test Results**

**Preliminary positive** - One or more of the same POC/Rapid tests were reactive and none are non-reactive and no supplemental testing was done at your agency

**Positive** - Two or more different (orthogonal) POC/Rapid tests are reactive and none are non-reactive and no laboratory-based supplemental testing was done

**Negative** - One or more POC/Rapid tests are non-reactive and none are reactive and no supplemental testing was done

**Discordant** - One or more POC/Rapid tests are reactive and one or more are non-reactive and no laboratory-based supplemental testing was done

**Invalid** - A CLIA-waived POC/Rapid test result cannot be confirmed due to conditions related to errors in the testing technology, specimen collection, or transport

**Value Definition for Inconclusive Lab Result**

**Inconclusive, further testing needed** - A blood sample was sent to a lab but a result could not be determined. Reasons include: hemolyzed sample; the lab report indicates "status undetermined"; or the lab report recommends repeat testing. Any questions contact Meghan Furnari at (919) 755-3147 or Meghan.Furnari@dhhs.nc.gov

**Value Definitions for New vs. Previous Dx**

**New diagnosis, verified** - The HIV surveillance system was checked and no prior report was found and there is no indication of a previous diagnosis by either client self report (if the client was asked) or review of other data sources (if other data sources were checked).

**New diagnosis, not verified** - The HIV surveillance system was not checked and the classification of new diagnosis is based only on no indication of a previous positive HIV test by client self-report or review of other data sources.

**Previous diagnosis** - Previously reported to the HIV surveillance system or the client reports a previous positive HIV test or evidence of a previous positive test is found on review of other data sources.

**Unable to determine** - The HIV surveillance system not checked

<b>9 State Health Department Entry Only</b> <i>(complete for persons testing POSITIVE for HIV)</i>
eHARS State Number
eHARS City/County Number
New or Previous diagnosis? <input type="radio"/> New diagnosis, verified <input type="radio"/> Previous diagnosis <input type="radio"/> New diagnosis, not verified <input type="radio"/> Unable to determine
<div style="border: 1px solid black; padding: 5px;">                 Has the client seen a medical care provider in the past six months for HIV treatment?  <input type="radio"/> No      <input type="radio"/> Declined to Answer  <input type="radio"/> Yes      <input type="radio"/> Don't know             </div>
Partner Services Case Number
Was the client interviewed for Partner Services? <input type="radio"/> Yes, by a health department specialist <input type="radio"/> Yes, by a non-health department person trained by the health department to conduct partner services <input type="radio"/> No <input type="radio"/> Don't Know
<div style="border: 1px solid black; padding: 5px; display: inline-block;">                 If Yes, Date of Interview:                  _____ / _____ / _____             </div>

**Notes**

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# Evaluation Web<sup>®</sup> HIV Testing Data Form – NORTH CAROLINA

## Data Collection / Data Entry Procedures

1. **Use Form for All HIV Testing Events as of 01/01/19**
  - a. Applies to agencies and health departments funded or supported through the following:
    - i. Expanded Testing (Community Health Centers, Emergency Departments, Jails)
    - ii. Integrated Targeted Testing (ITTS)
    - iii. Rapid Kits Only – *when the test event involves the Rapid Kit/s provided by the State Prevention Program*
    - iv. Substance Abuse Centers (SAC)
  - b. Does NOT apply to regular testing in health department clinics
  - c. If a client declines HIV testing but is tested for other STIs, still use the form to enter the data
  - d. Use this form to *collect your data as of 1/1/2019*
2. **Printing and Copying**
  - a. The form can be printed locally and it is fine to photocopy it as well
  - b. We suggest that you fill in a form with your Agency ID and photocopy that is 2-sided
  - c. If you are doing any point of care (POC)/Rapid testing for HIV, Syphilis or HCV, you will need all 3 pages of the form because we are using Local Use Fields in Section 8 to track rapid testing
  - d. If you are NOT doing any POC/Rapid tests, you can use just pages 1-2
3. **Use with Agency Intake Forms**
  - a. Data should ultimately be recorded on the HIV Testing Data Form but if your agency uses a separate client or counselor 'intake' form first, that is fine
  - b. If so, make sure that all of the necessary data elements are covered on your local intake form and transferred to the HIV Testing Data Form.
  - c. The HIV Testing Data Form is designed to be filled out by a trained HIV test counselor
    - i. Please do not give this form to the tested client for them to fill out
    - ii. Any forms that are given to clients to fill out should be designed specifically for that purpose
4. **Format**
  - a. The order of the data elements follows the order of data entry in Evaluation Web
    - i. The order may not make the most sense for client encounters so you will need to skip around a little
    - ii. Oval bubbles mean "select only one" and square boxes mean "check all that apply"
    - iii. Note that Name and full Date of Birth are needed by CDB in order to look up the client in the Surveillance system in the event that the person tests positive for HIV. Evaluation Web does *not* capture name and requires only year of birth

**5. Data to Collect at Time of Testing**

- a. Name and Program information at the top
  - i. Repeat Client name on page 2 and page 3
  - ii. Skip Form ID – this ID number is created by Evaluation Web at the time of data entry
- b. Section 1 – Agency and Client Information
  - i. Program Announcement = PS18-1802
- c. Section 2 – Testing Information
  - i. HIV Test Election = Confidential
  - ii. HIV Test Type
    - 1. For Rapid testing complete CLIA-waived point-of-care (POC)/Rapid test/s
    - 2. For lab testing complete Laboratory-based Test
    - 3. If both Rapid/POC testing and Laboratory-based testing was done
      - a. Fill out both results sections
      - b. Complete Local Use Field 1 on page 3 “RHIV”
- d. Section 3 – Negative Test Result
  - i. Collect information for all tested persons
  - ii. Use the Eval Web PrEP Questions Guidance to complete the screened, eligible, referral given questions
  - iii. If the client is eligible for PrEP based on the NC PrEP Criteria, please complete the PrEP Referral and Linkage Form and accompanying guidance
  - iv. Do Not complete the last question “Was the client provided with services to assist with linkage to a PrEP provider?” as this will be completed only by PrEP Coordinators
  - v. The HIV Testing and PrEP Data Collection Guide provides an overview of PrEP and HIV Prevention testing
- e. Section 5 – Additional Tests
  - i. Fill out which tests were performed and wait for results
  - ii. If Syphilis Rapid Test was done, record results and complete Local Use Field 2 on page 3 “RSYPH”
  - iii. If HCV Rapid Test was done, record results and complete Local Use Field 3 on page 3 “RHCV”
- f. Section 6 – PrEP Awareness & Priority Populations
- g. Section 7 – Essential Support Services
  - i. Complete the last 4 rows of questions; this includes health benefits navigation and enrollment, evidence-based risk-reduction intervention, behavioral health services, and social services
- h. Section 8 – Local Use Fields. As of now, we are using fields 1, 2, 3 to indicate rapid testing for HIV, Syphilis, HCV. Local Use Field 4 is to be completed only by PrEP Coordinators. Local Use Fields 1-4 have been assigned and are not available for any other use. Please refrain from assigning or using Local use Fields 5-8.

- 6. Fill Out Separate Form(s) to Order HIV and STI Testing from Laboratories**
- a. For HIV and HCV testing at the State Laboratory of Public Health (SLPH), use the current HIV testing form.
    - i. You can skip Test1, Test2 and the behavioral risk factors
    - ii. Send Lab form and blood sample to SLPH for testing
  - b. For Syphilis, Chlamydia, Gonorrhea testing, fill out form(s) for appropriate State, County, or Private Lab
    - i. Send Lab form and blood sample to appropriate lab for testing

- 7. Agency Filing System Needed**
- a. Forms awaiting Laboratory Results
  - b. Forms with all results complete awaiting data entry
  - c. Forms that have been entered
  - d. Forms for HIV-Positives that have been copied and sent to CDB
  - e. All forms need to be kept in a secure, locked location
    - i. Preferably a locked cabinet within a locked room

- 8. Record All Results on HIV Testing Data Form**
- a. Record POC/Rapid test results immediately
  - b. Record Lab test results as they come in
    - i. If HIV-positive, fill out as much of Section 4 – Positive Test Result as you are able; it is fine if you don't know all of it, Communicable Disease Branch staff will check the surveillance system for some of these answers
    - ii. Keep forms filed as above until all results have been recorded
  - c. When ALL HIV/STI test results have been recorded, file separately:
    - i. HIV Negative, Invalid tests (regardless of results from other STI testing)
      1. These forms are now ready for data entry
      2. Further sort the forms by Program Funding and Region  
This will make data entry easier (see below)
    - ii. HIV Positive, Preliminary Positive, Discordant, and Inconclusive HIV tests
      1. Make a photocopy and send to us in CDB  
Place forms in an inner envelope that is sealed and marked "Confidential"  
Place that envelope inside an outer envelope and send to:  
Meghan Furnari, MA  
Prevention Program  
1200 Front St, Suite 104  
Raleigh, NC 27609
      2. CDB Staff will check the HIV Case Surveillance system and will fill out the remainder of Section 4 (Positive Test Result) and Section 9 (Health Department Use Only)
      3. CDB Staff will then enter the forms in Evaluation Web

**9. Entry into Evaluation Web – please use Google Chrome as your web browser, Firefox and Microsoft Edge are alternative options as well**

- a. Agencies will enter the data for the HIV-Negative forms
  - i. Enter regularly, preferably several times per month.
  - ii. Enter stacks of similar Program/Region together.  
The first data field chosen will be called “Program” which is a combination of the CDB Program/Funding and the Region. Many agencies will only have one or two choices.
  - iii. Indicate that each form has been entered.  
As each form is entered, the Evaluation Web system will generate a Form ID for each form entered. Since EW does not include data on Client Name or full Date of Birth, the Form ID is the only unique identifier that will link a database record to a form. Agency staff must write the Form ID on the HIV Testing Data Form during data entry. If the client has been referred to PrEP the Form ID must be noted on the PrEP Referral and Linkage Form as well.
  - iv. File entered forms. We suggest filing them by date.
    1. For now, ***please keep all forms.***  
We will verify the State records retention policy and advise further.
- b. CDB staff will enter the data for the HIV-Positives, Preliminary Positives, Inconclusives, and Discordant HIV results.

**10. Rapid Testing Data Procedures - Recap**

- a. HIV POC Rapid Test(s) only - Negatives
  - i. Use the POC Rapid Test Result in Section 2
- b. HIV POC Rapid Test(s) only - Positives
  - i. Make a copy of the form and send the copy to CDB. File your own copy. CDB will enter data.
- c. HIV POC Rapid Test(s) AND Laboratory-based test – Negatives
  - i. Fill out information for both types of testing.
  - ii. In Evaluation Web, choose Laboratory-based testing and enter the Lab result.
  - iii. Enter RHIV in Local Use Field 1 on page 3
- d. HIV POC Rapid Test(s) AND Laboratory-based test – Positives
  - i. Fill out information for both types of testing in Section 2.
  - ii. Enter RHIV in Local Use Field 1 on page 3
  - iii. Make a copy of the form and send the copy to CDB. File your own copy. CDB will enter data.
- e. Syphilis POC Rapid Test
  - i. Enter test result (all results)
  - ii. Enter RSYPH in Local Use Field 2 on page 3
- f. Hepatitis C POC Rapid Test
  - i. Enter test result (all results)
  - ii. Enter RHCV in Local Use Field 3 on page 3

**Division of Public Health  
Confidentiality Agreement**

**Effective Date: May 1, 2011**

Ensuring the confidentiality of all health reports, records, and files containing patient names and other individually identifying information is of critical importance in the Division of Public Health. Breaches of confidentiality could undermine public trust in the Public Health Division and thereby hinder efforts to prevent and control morbidity and mortality and to protect the public from disease and injury.

Federal and state laws, including the HIPAA Privacy Rule and NC General Statute § 130A-12, provides for the protection, privacy, and security individual health information.

These laws provide requirements to ensure that the protection of certain individually identifiable health information that is created, received, and maintained in any form or medium, by the North Carolina Department of Health and Human Services (DHHS) and the Division of Public health, is safeguarded and protected

Employees of the Division of Public Health may only use and disclose individually identifiable health information as provided by and subject to all of the limitations and requirements specified in the DHHS Policies and Procedures Manual and in the Division of Public Health privacy policies and procedures as defined in the Division of Public Health Privacy and Security Manual.

**Employee Acknowledgement:**

- I understand that I may have direct or indirect access to confidential individually identifiable health information in the course of performing my work activities and I agree to protect the confidentiality of any individually identifiable health information to which I may have access.
- I shall adhere to all the Division business procedures that provide for minimizing the intentional and unintentional conveyance of individually identifiable information to unauthorized parties through written or oral interactions.
- I must make all reasonable efforts to limit individually identifiable health information to that which is *minimally necessary* to accomplish the intended purpose for the use, disclosure, or request for information.
- I understand that there are state and federal laws and regulations that ensure the confidentiality of an individual's identifying health information.
- I understand that there are DHHS and Division policies and procedures with which I am required to comply related to the protection of individually identifiable health information. Should questions arise about how to protect information to which I have access, I will immediately notify my supervisor and/or the DPH Privacy Official.
- I understand that my failure to observe and abide by these policies and procedures may result in disciplinary action, which may include dismissal and/or contract termination, and/or punishment by fine and/or imprisonment. I understand that there may be sanctions resulting from failure to comply with DHHS and Division privacy policies and procedures and the Division shall use the procedures in the State Personnel Manual to apply appropriate sanctions against members of its staff who fail to comply with these privacy policies and procedures.
- I have been informed that this signed acknowledgement will be retained on file for future reference.

**I have read the above confidentiality statement and understand its implications for my position in the Division of Public Health.**

PRINT NAME: \_\_\_\_\_

Employee or Contractor Signature: \_\_\_\_\_ Date: \_\_\_\_\_

### Rapid HIV HCV Syphilis Testing Comparison Chart

		OraSure Technologies OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test	Alere Determine™ HIV-1/2 Ag/Ab Combo	Diagnostics Direct Syphilis Health Check™	OraSure Technologies OraQuick® HCV Rapid Antibody Test	INSTI HIV-1/HIV-2 Antibody Test
Specimen Collection	Venipuncture Whole Blood	Yes	Yes	No	No	Yes
	Fingerstick Whole Blood	Yes	Yes	Yes	Yes	Yes
	Plasma	Yes	Yes	Yes	Yes	Yes
	Serum	No	Yes	Yes	Yes	No
	Oral Fluid	Yes	No	No	No	No
Complexity	Waived	Oral fluid, Fingerstick whole blood, Venipuncture Whole Blood	Fingerstick whole blood	Fingerstick whole blood	Fingerstick whole blood, Venipuncture whole blood	Fingerstick whole blood
	Moderate	Plasma	Venipuncture whole blood, Plasma, Serum	Venipuncture whole blood, Plasma, Serum	N/A	Venipuncture whole blood, Plasma
Shelf Life	Control Kits	12 months unopened 8 weeks opened	18 months opened or unopened	24 months	12 months unopened 8 weeks opened	12 months
	Test Kits	24 months	24 months	24 Months	18 months	15 months
Temperature Requirements	Control Storage	2° to 8°C (35° to 46°F)	2° to 8°C (35° to 46°F)	2° to 8°C (35° to 46°F)	2° to 8°C (35° to 46°F)	2° to 30°C (35.6°-86°F)
	Test Kit Storage	2 to 27°C (35° to 80°F)	2 to 30°C (35° to 86°F)	4° to 30°C (39.2°-86°F)	2° to 30°C (35.6°-86°F)	2 to 30°C (35° to 86°F)
	Testing Environment	15° to 37°C (59° to 99°F)	15° to 30°C (59° to 86°F)	20° to 26°C (68° to 78.8°F)	15° to 37°C (59° to 99°F)	15° to 30°C (59°-86°F)
Time	Minimum Time for Development	20 minutes	20 minutes	10 minutes	20 minutes	1 minute
	Read Window	20 to 40 minutes	20 to 30 minutes	10 to 15 minutes	20 to 40 minutes	5 minutes
Sensitivity HIV-1 (95% confidence limits)	Venipuncture Whole Blood	99.6%	99.9%			99.9%
	Fingerstick Whole Blood	99.6%	99.9%	98%	98%	99.8%
	Plasma	99.6%	99.9%	99.9%	98%	99.9%
	Serum	N/A	99.9%	N/A	98%	N/A
	Oral Fluid	99.3%	N/A	N/A	N/A	N/A

		OraSure Technologies OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test	Alere Determine™ HIV-1/2 Ag/Ab Combo	Diagnostics Direct Syphilis Health Check™	OraSure Technologies OraQuick® HCV Rapid Antibody Test	INSTI® HIV-1/HIV-2 Antibody Test
Specificity (95% confidence limits)	Venipuncture Whole Blood	100%	99.7%	100%	98%	100%
	Fingerstick Whole Blood	100%	99.8%	99.5%	98%	99.5%
	Plasma	99.9%	99.7%	100%	98%	100%
	Serum	N/A	99.6%	N/A	98%	N/A
	Oral Fluid	99.8%	N/A	N/A	N/A	N/A
Detection Time Frame* Days after HIV-1 RNA is detectable (~10 days)		23.7 days	Antigens 14-15 days; antigen & antibodies 21-28 days after infection (early infection).	N/A	N/A	21 days
HIV-2 Detection		Yes	Yes	N/A	N/A	Yes
Materials Provided in Test Kit (not including manufacturer supplied paperwork)		Test device, developer solution, reusable test stands, specimen collection loops	Test device, chase buffer, disposable capillary tubes, disposable workstations	Test device, disposable pipettes, diluent in dropper bottle containing saline buffer	Test device, buffer, pipette, moisture pad	Test device, membrane Unit, bottle 1, sample diluent (1.5ml), Bottle 2, color developer (1.5ml), bottle 3, clarifying solution (1.5ml), lancet, capillary test pipette, alcohol swab
Available Kit Sizes		100 test kits 25 test kits	100 test kits 25 test kits	20 test kits	25 test kits	50 test kits
Generation of detection		3rd generation lateral-flow	4th generation lateral-flow	N/A	N/A	3rd generation immunofiltration "flow-through"

\*Median of 95% confidence intervals representing the estimated ranges of days that HIV-1 tests begin to detect HIV-1 infection AFTER HIV-1 RNA is detectable. The interval between HIV infection and the appearance of HIV-1 RNA is estimates to be around 10 days, but the absolute range is not yet known. See [https://www.cdc.gov/hiv/pdf/testing/hiv-tests-advantages-disadvantages\\_1.pdf](https://www.cdc.gov/hiv/pdf/testing/hiv-tests-advantages-disadvantages_1.pdf) for further details.

Please feel free to copy, duplicate, and print the following temperature logs, results logs, and recording logs.

### Rapid Testing Kit Storage Temperature Log

Thermometer location:
Rapid test kit brands monitored:
Acceptable temperature range: 8°C to 27°C (46°F to 80°F). Recommended to keep kits at room temperature.
Month/Year

Day	Temperature	Min	Max	Initials	Day	Temperature	Min	Max	Initials
1					17				
2					18				
3					19				
4					20				
5					21				
6					22				
7					23				
8					24				
9					25				
10					26				
11					27				
12					28				
13					29				
14					30				
15					31				
16									

**NOTE:** Periodically (e.g., every six months) check thermometer performance and document. Min/Max thermometers maintain a record of the highest and lowest temperature recorded during an observation period and are highly recommended.

Kits should be checked at least once a week with a preference to daily monitoring. Weekly monitoring should be performed with a min/max thermometer in place.

**Corrective Action**

Date	Action Taken	Initials

Reviewed by:	Date:
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### Rapid Testing Control Storage Temperature Log

Thermometer location:
Rapid test kit brands monitored:
Acceptable temperature range: 2°C to 8°C (35°F to 46°F)
Month/Year

Day	Temperature	Min	Max	Initials	Day	Temperature	Min	Max	Initials
1					17				
2					18				
3					19				
4					20				
5					21				
6					22				
7					23				
8					24				
9					25				
10					26				
11					27				
12					28				
13					29				
14					30				
15					31				
16									

**NOTE:** Periodically (e.g., every six months) check thermometer performance and document. Min/Max thermometers maintain a record of the highest and lowest temperature recorded during an observation period and are highly recommended.

Controls should be checked at least once a week with a preference to daily monitoring. Weekly monitoring should be performed with a min/max thermometer in place.

**Corrective Action**

Date	Action Taken	Initials

Reviewed by:	Date:
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### Rapid Testing Kit Results Log

Client ID*	Date/Time	Test Room/Area Temp	Kit name and lot#	Kit exp. date	Specimen type	Time Test Started	Time Test Interpreted	Test Result	Confirm. Test Required?	Date Results Given	Initials of Tester
			Brand:		<input type="checkbox"/> Blood			<input type="checkbox"/> Non-reactive <input type="checkbox"/> Reactive <input type="checkbox"/> Invalid	<input type="checkbox"/> Yes <input type="checkbox"/> No		
			Lot:		<input type="checkbox"/> Oral						
			Brand:		<input type="checkbox"/> Blood			<input type="checkbox"/> Non-reactive <input type="checkbox"/> Reactive <input type="checkbox"/> Invalid	<input type="checkbox"/> Yes <input type="checkbox"/> No		
			Lot:		<input type="checkbox"/> Oral						
			Brand:		<input type="checkbox"/> Blood			<input type="checkbox"/> Non-reactive <input type="checkbox"/> Reactive <input type="checkbox"/> Invalid	<input type="checkbox"/> Yes <input type="checkbox"/> No		
			Lot:		<input type="checkbox"/> Oral						
			Brand:		<input type="checkbox"/> Blood			<input type="checkbox"/> Non-reactive <input type="checkbox"/> Reactive <input type="checkbox"/> Invalid	<input type="checkbox"/> Yes <input type="checkbox"/> No		
			Lot:		<input type="checkbox"/> Oral						
			Brand:		<input type="checkbox"/> Blood			<input type="checkbox"/> Non-reactive <input type="checkbox"/> Reactive <input type="checkbox"/> Invalid	<input type="checkbox"/> Yes <input type="checkbox"/> No		
			Lot:		<input type="checkbox"/> Oral						
			Brand:		<input type="checkbox"/> Blood			<input type="checkbox"/> Non-reactive <input type="checkbox"/> Reactive <input type="checkbox"/> Invalid	<input type="checkbox"/> Yes <input type="checkbox"/> No		
			Lot:		<input type="checkbox"/> Oral						

\*Unique Client ID

<b>Reviewed by:</b>	<b>Date:</b>
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### Rapid Testing Control Results Log

Date	Time	Test Area Temp	Kit name and lot#	Kit exp. date	Control lot#	Control exp. date	Date controls opened	Reason running controls*	Negative Control Results	Positive Control Results	Initials of Tester
			Brand:							HIV-1:	
			Lot:							HIV-2:	
			Brand:							HIV-1:	
			Lot:							HIV-2:	
			Brand:							HIV-1:	
			Lot:							HIV-2:	
			Brand:							HIV-1:	
			Lot:							HIV-2:	
			Brand:							HIV-1:	
			Lot:							HIV-2:	

\*Options for reason running controls: new user, new shipment, new lot#, out of range kits, out of range testing area, training

#### Corrective Action

Date	Action Taken	Initials

<b>Reviewed by:</b>	<b>Date:</b>
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### Rapid HIV Testing Training Records Log

Please list the name of each staff member who conducts rapid testing. Indicate the date of their most recent training and who provided the training. Keep a record of this document for internal use and update as needed. **As different brands of rapid test kits come in, make sure to edit this internal template to reflect the current rapid test brand availability.**

Staff Member Name	OraQuick HIV/HCV	Determine Combo	INSTI	Syphilis Health Check	Whetstone	Safe Work Habits	Bloodborne Pathogens
	Date: Provided by: <input type="checkbox"/> State <input type="checkbox"/> Manufacturer <input type="checkbox"/> Internal Agency <input type="checkbox"/> Other	Date: Provided by: <input type="checkbox"/> State <input type="checkbox"/> Manufacturer <input type="checkbox"/> Internal Agency <input type="checkbox"/> Other	Date: Provided by: <input type="checkbox"/> State <input type="checkbox"/> Manufacturer <input type="checkbox"/> Internal Agency <input type="checkbox"/> Other	Date: Provided by: <input type="checkbox"/> State <input type="checkbox"/> Manufacturer <input type="checkbox"/> Internal Agency <input type="checkbox"/> Other	Date: Provided by: <input type="checkbox"/> State <input type="checkbox"/> Manufacturer <input type="checkbox"/> Internal Agency <input type="checkbox"/> Other	Date: Provided by: <input type="checkbox"/> State <input type="checkbox"/> Manufacturer <input type="checkbox"/> Internal Agency <input type="checkbox"/> Other	Date: Provided by: <input type="checkbox"/> State <input type="checkbox"/> Manufacturer <input type="checkbox"/> Internal Agency <input type="checkbox"/> Other
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# RAPID TEST KIT INVENTORY

(to be completed on the last business day of every month)

Agency Name:

Name of Staff:

Completed for (Month/Year):

Date Completed:

Brand Name	# Test Kits on Hand	Test Kits Expiration Date	# Controls on Hand	Controls Expiration Date
OraQuick HIV				
Determine Combo				
INSTI				
Syphilis Health Check				
OraQuick HCV				
Indicate Other Brands Below:				



## Sample Standing Orders for HIV Rapid Tests

{Physician Letterhead}

{Date}

{Agency Name and address}

To Whom It May Concern:

The following are Standing Orders for {Name of Agency} regarding HIV pre- and post-test counseling, and, HIV rapid testing.

{Name of Executive Director} is appointed the sole person responsible for ensuring that these standing orders are carried out in full on behalf and in the authority of {Name of Physician}.

All HIV tests will be administered by and under the authority of {Name of Physician}. {Name of Executive Director} will ensure that assigned staff from {Name of Agency} have attended the Communicable Disease Branch approved HIV Counseling, Testing and Referral (CTR) training ([www.whetstoneconsultations.com](http://www.whetstoneconsultations.com)) and any Branch approved rapid HIV testing training.

Designated staff representing {Name of Agency} may collect appropriate specimens for HIV rapid tests and interpret rapid test results at specified nontraditional test sites in {Name of County} and during special targeted testing events.

{Name of Agency} must make post-test counseling available and all preliminary HIV-positive test results must be linked to confirmatory HIV testing. Per NC GS 130A-144(d), all clients with preliminary HIV-positive results must be given control measures. Designated staff will provide follow-up according to agency's policies and procedures.

Signed by {Name of Physician}

## NC DHHS Communicable Disease Branch

### HIV/STD/HCV Prevention Program

Pete Moore, Manager, HIV/STD Prevention Program

[pete.moore@dhhs.nc.gov](mailto:pete.moore@dhhs.nc.gov)

919-755-3140

### Rapid Testing Team

Carlotta McNeill, Rapid Testing Coordinator

[carlotta.mcneill@dhhs.nc.gov](mailto:carlotta.mcneill@dhhs.nc.gov)

919-755-3144

Marti Eisenberg, Integrated Targeting Testing Services Coordinator/Rapid Testing

[marti.eisenberg@dhhs.nc.gov](mailto:marti.eisenberg@dhhs.nc.gov)

919-755-3145

Samantha Ty, Rapid Testing Monitor

[samantha.ty@dhhs.nc.gov](mailto:samantha.ty@dhhs.nc.gov)

919-755-3153

### HIV/STD/HCV Prevention Program Data Team

Meghan Furnari, Prevention Data Manager

[meghan.furnari@dhhs.nc.gov](mailto:meghan.furnari@dhhs.nc.gov)

919-755-3147